EPA REGISTRATION NUMBER 46597-4
RECORDS PRIOR TO 11/03/2016

Receipt for Section 3

S: 993451 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 91685 PURICORE INC

Risk Manager: Antimicrobials Division, Risk Management Team 32

Product #: 91685-R Product Name: ProduceFresh Produce Quality Treatment Solu

Me Too Section3:

Me Too Product Name:

Fee For Service: Yes / No

Billable: Yes / No

Print Letter

Enter More Information

Tracking

Application Date: 13-Oct-2016

OPP Rec'vd Date: 14-Oct-2016

Front End Date: 14-Oct-2016

Risk Manager Send Date: 14-Oct-2016

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

New Ingredient:

Receipt Description:

Re-Submission to EPA product chemistry review of producefresh

Receipt Content	Des
CSF	

View/Edit

Denson

~~362~~

Resubmission existing PRIA

PRIA DUE Date:

Exponent®

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

October 13, 2016

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: **Response to EPA Product Chemistry Review of ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R)**

Dear Demson,

On behalf of our client Puricore, Exponent is submitting the enclosed response to EPA's review of the product chemistry data submitted to support the pending registration application for ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol 91685-R). In support of this response, please find enclosed the following:

- Copy of the EPA Product Chemistry Review, dated September 22, 2016;
- Updated Confidential Statement of Formula; and
- Detailed response to the EPA's findings.

Please note that the information in this submission is considered ***Confidential Business Information*** and must not be disclosed to any party outside of EPA. Should you have any questions or need additional information regarding the enclosed response, please do not hesitate to contact me via telephone at 202-772-4916 or via email at cdaniels@exponent.com.

Sincerely,

Carrie Daniels
Authorized Representative of
Puricore Inc.

Enclosures

cc: Srinivas Gowda, EPA
Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
James Messina, Exponent

Response to EPA Findings in the Product Chemistry Review dated September 22, 2016 for ProduceFresh Produce Quality Treatment Solution (EPA File Symbol 91685-R)

1. EPA Reg. No. **91685-R** is an end-use product. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system.

   No response needed.

2. The basic CSF is not acceptable due to the following:

   a. The density value placed in box 7 is not supported with study data, see Table for subgroup B, GLN 830.7300.

      Registrant response: The density value range has been revised on the CSF to 1.00 – 1.07 g/ml. This range includes the value 1.005 g/ml presented for GLN OCSPP 830.7300 in the Physical and Chemical Characteristics study (MRID 49672603).

   b. The active ingredient data shown in columns 13 and 14 without brackets are not in compliance with Product Identity and Composition data provided in MRID 49672601 for the ready to sell and distribution stage of the production process.

      Registrant response: The CSF has been revised to remove the active ingredient data without brackets. The revised CSF reflects the active ingredient concentration as described in GLN OCSPP 830.1550 Product Identity and Composition (MRID 49672601) when ProduceFresh is ready for sale and distribution.

   c. Total weight of formulation in box 17 and percentage by weight in the bottom of column 13b are not related to the stage of product production that is ready for sell and distribution.

      Registrant response: The CSF has been revised as described in 2b above. Therefore, the information in Box 17 and the bottom of column 13b are representative of the product when ready for sale and distribution.

   d. The certified limits for the active ingredient (0.54% / 0.27%) are not standard for the nominal concentration 0.45% and not supported with the study data provided in MRID 49672601 (0.5% / 0.3%). In turn, the study data are questionable, see Confidential Attachment, GRN 830.1750.

      Registrant response: The CSF has been revised to reflect the nominal concentration of 0.45% (matching the label), with upper and lower certified limits of 0.6% and 0.3%, respectively. These limits are wider than the standard upper and lower limits,

due to the chemical composition of this product. As described in the Group A Product Chemistry study (MRID 49672601, p. 26 of 35) ProduceFresh [redacted] This lower limit is further supported by the GLP storage stability data (MRID 49672604).

e. The formulation does not contain an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GLN 830.1670.

Registrant response: The Group A Product Chemistry study (MRID 49672601, p. 26 of 35) indicates that [redacted] during the production process. The reaction processes for the production of ProduceFresh are provided below.

[redacted]

Manufacturing process information may be entitled to confidential treatment

[redacted]

f. The formulation is not supported with data provided in section Description of Production/Formulation process of MRID 49672601, see Confidential Attachment, GRNs 830.1620 and 830.1650.

Registrant response: The responses to the questions above fully describe the Production and Formulation process and the revised CSF represents the formulation as sold.

3. Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

Registrant response: The CSF identifies [redacted] used in the production of ProduceFresh. While the Description of the Materials Used to Produce the Product does not specifically identify [redacted] as one of the starting materials, the CAS # and source [redacted] are identified on the CSF. Further, the CSF is found in the Group A Product Chemistry study (MRID 49672601) on page 24 of 35 under the Guideline requirement for 830.1600. Therefore, the Agency has the information necessary to satisfy this guideline requirement.

4. As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. The requirements of Guideline 830.1620 (Description of Production Process) are not satisfied.

Registrant response: With all products there will be time between the production and packaging of a product and its distribution into the market. There is no requirement under FIFRA to describe or quantify that time. Manufacturers must only ensure that their product is produced and distributed according to the specifications presented on the CSF. Puricore noted this time delay in describing the rationale for [redacted]

The information presented under OCSPP Guideline 830.1620 indicates multiple quality control measurements throughout the production process to ensure that ProduceFresh is meeting the EPA approved product specifications. These steps ensure that the product that is manufactured, sold, and distributed is within the specifications presented on the

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

CSF and in compliance with FIFRA. The OCSPP Guideline 830.1620 requirement has been fulfilled.

5. Discussion of Formation of Impurities is not supported with chemical equations describing the transformation of starting materials into the final product and by-products and the Preliminary Analysis data. No assessment was conducted to get an amount of mentioned [redacted] The requirements of Guideline 830.1670 are not satisfied.

Registrant response: The Preliminary Analysis did not include an assessment of [redacted] Please also see the response to question 2e above, which provides the chemical equations describing the transformation of the starting materials into the final product and by-products.

6. Preliminary analysis study is not acceptable because the analysis did not evaluate an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670. The requirements of Guideline 830.1700 are not satisfied.

Registrant response: This question has been answered in the response for question 5 above. The requirements of Guideline 830.1700 have been satisfied.

7. As per MRID 49672601, the upper certified limit has been fitted equal to production concentration, and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit is based on accelerated storage stability test result that is not acceptable due to the temperature deviation from the standard requirements (see Finding 8 below). Therefore, the requirements of Guideline 830.1750 are not acceptable.

Registrant response: The standard upper and lower limits (+/- 10%) for a nominal concentration of 0.45% would be 0.50% (UL) and 0.41% (LL). [redacted] The lower limit is further supported by the storage stability data (MRID 49672604), which shows that a starting concentration of 0.47% can be expected to degrade to 0.33%, which is well outside of the standard lower limit of 0.41%. Based on the known properties of HOCl and other similar products (sodium hypochlorite), the wider certified limits are justified to ensure that the product stays within the product specification.

8. As per MRID 49672604 issued 08/21/2015, Storage Stability and Corrosion Characteristics accelerated tests were conducted at temperature 40^0C during 30 days. The

Manufacturing process information may be entitled to confidential treatment

condition of the tests is based on old EPA internal instruction issued 3/31/2011 that is no longer valid. The current requirements for an accelerated test are provided in EPA Memorandum dated 11/16/2012. Therefore, the condition of the tests does not satisfy the requirements of Guidelines 830.6317 and 830.6320, respectively.
In accordance with the Memorandum, for Storage Stability and Corrosion Characteristics, the registrant should provide results for a minimum of 1 year from a GLP compliant storage stability and corrosion characteristics study. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year.
Or
Conduct a Storage Stability and Corrosion Characteristics study for 14 days at elevated temperature 54°C±2^{0}C. The test shall be conducted in compliance with the Good Laboratory Practice standards (GLP) under 40 CFR Part 160.135(b). The concentration(s) of the active ingredient(s) in the product shall be determined at the beginning of the test period and after 14 days, using a validated analytical method. The product should be quantitatively analyzed for active ingredient content and changes in impurities as a result of degradation or packaging deterioration over the test period. Either test should be conducted with the product in its commercial package or in smaller packages of the same construction and materials.

Registrant response: While the Agency has issued revised guidance regarding the protocol for the accelerated storage stability study, the data that Puricore has generated were conducted according to GLP standards and are reflective of the March 31, 2011 EPA criteria. Additionally, the Agency noted in the January 25, 2011 memorandum regarding the Accelerated versus One-year Storage Stability and Corrosion Characteristics studies that they had reviewed an estimated 50 studies conducted at temperature ranges from 40°C to 54°C, at durations of 14 days, and up to one month or one year. The Agency noted that "...all accelerated data are comparable to results obtained in studies conducted for an extended storage time." There is no indication that the Agency noted a difference between results for 40°C as compared to 54°C.

Additionally, the current guidelines for the standard one-year storage stability study (OCSPP 830.6317; page 4 item C) indicate that "The test parameters may be expanded to include accelerated conditions, such as elevated temperature (or 40°C – 54°C)...". This guidance reflects flexibility in the acceptable temperatures for accelerated testing. We are aware of other storage stability and corrosion characteristics studies conducted at 40°C for 30 days that have been accepted by the Agency to fulfill the storage stability data requirement for EPA registered antimicrobial products.

Lastly, the results of the available GLP accelerated storage stability and corrosion characteristics study are consistent with what would be expected for this active ingredient. The data demonstrated an expected decline in percent of active ingredient following storage at 40°C for 30-days. One-year storage stability data generated at the

standard temperature range of 20°C to 25°C would be expected to be similar to the submitted accelerated data.

9. Data reported in MRID #s. 496726-01,-03, and 498402-01 partially satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

Registrant response: Each of the deficiencies noted in this EPA memorandum have been addressed in this response. Therefore, the product chemistry data requirements for Subgroups A and B are satisfied.

10. The Ingredient Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 9-6. However, a note under asterisk mark (*) must be deleted because 4500 ppm of Hypochlorous Acid cannot contain 6000 ppm of FAC. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

Registrant response: The asterisk statement indicating 6000 ppm Free Available Chlorine (FAC), based on 4500 ppm Hypochlorous Acid (HOCl) in the ingredient statement is correct and should remain on the label. The Preliminary Analysis study (MRID 49672602) indicates that the molecular weight of HOCl is 52.46 and the molecular weight of FAC is 70.91. Using the ratio of the molecular weights (1.35), 4500 ppm HOCl is equal to 6000 ppm FAC. This conversion factor is used in the Preliminary Analysis to present the amount of HOCl in each of the five batches tested (ranging from 0.42% to 0.50%) and the corresponding amount of FAC (ranging from 0.56% to 0.68%).

CONCLUSION:

The basic CSF, dated 2/23/2016, for EPA Reg. No. 91685-R is not acceptable (Finding 2). The registrant will have satisfied the product chemistry requirements after submission of the corrected basic CSF that is harmonized and supported with study data (Findings 3-5, 7). The impurities that accompanied the production process with a nominal concentration greater than 0.1% must be fully described in section Discussion of formation of impurities (Finding 5) and assessed in Preliminary Analysis (Finding 6) and shown on the CSF. The Storage Stability and Corrosion Characteristics data must be evaluated under current OCSPP requirements (Finding 8).

Finally, Puricore notes that there are several studies that are marked as N/A in the Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190) table below (shaded in yellow). However, these studies have been addressed via a waiver rationale (MRID 49840201), as required by EPA in the technical screen for this registration submission dated February 9, 2016, and should be marked as waived. These studies are: 830.6315 Flammability/ Flame Extension, 830.6316 Explodability, 830.6319 Miscibility, 830.6321 Dielectric Breakdown Voltage.

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Colorless to slightly yellow	49672603	Y
.6303 Physical State	Clear liquid	49672603	Y
.6304 Odor	Chlorine-like	49672603	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	This product will not come into contact with metal or metal ions.	49840201	N/A
.6314 Oxidation/Reduction Chemical Incompatibility	Agent / Compatibility: Water – compatible; 10% Monoammonium phosphate solution – compatible; Iron powder – compatible; 10% Potassium permanganate solution – compatible; Kerosene – compatible	49672603	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	49840201	N/A
.6316 Explodability	The product is not potentially explosive.	49840201	N/A
.6317 Storage Stability	Stable for 30 days at T=40^{0}C	49672604	N (See Finding 8)
.6319 Miscibility	The product is not to be mixed with petroleum distillate.	49840201	N/A
.6320 Corrosion Characteristics	Not corrosive after 1 month of storage at T=40^{0}C	49672604	N (See Finding 8)
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	49840201	N/A
.7000 pH	5.44	49672603	Y
	4.0 – 6.0	CSF	
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	1.0 Centistokes @20.0°C; 0.7 Centistokes @40.0°C	49672603	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.005 g/mL @ 20°C	49672603	Y
	1.01 – 1.07 g/mL	CSF	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Notes to PM:

1. The substance tested for group B data and described in MRID 49672603 has a higher level of the nominal concentration compared with the same on the CSF and the label (0.65% vs 0.45%). Additionally, the test substance contains an impurity [redacted] that is not shown in the formulation and has not been evaluated during the studies. Thus, the group B data are questionable.

   Registrant response: The percentage of hypochlorous acid used in the Group B product chemistry study is 0.69% FAC as stated on the Certificate of Conformance (page 25 of 25). Converting the amount of FAC to hypochlorous acid, there is 0.51% hypochlorous acid in the test material, which is within the proposed upper limit presented on the CSF. The ratio of the molecular weights for FAC and hypochlorous acid was described in question 10 above. Using the ratio (1.35), 0.51% HOCl is equal to 0.69% FAC.

   Further, EPA accepted Group B Product Chemistry data (MRID 49672703) supporting the registration of FloraFresh (EPA Reg No 91685-2), containing 0.3% hypochlorous acid, resulted in virtually identical data. The following summary table provides a side-by-side comparison of the available product chemistry data demonstrating that small differences in the amount of hypochlorous acid does not affect the product chemistry profile.

Physical/Chemical Characteristic	FloraFresh Study (MRID 49672703) (0.3% HOCl)	ProduceFresh Study (MRID 49672603) (0.5% HOCl)
Color	Very light yellowish	Colorless to slightly pale yellow
Physical State	Clear liquid	Clear liquid
Odor	Acid-like	Chlorine-like
Oxidation/Reduction	Compatible	Compatible
pH (1% w/w)	5.46	5.44
Viscosity (Kinematic)	1.0 (20°C)/0.7 (40°C)	1.0 (20°C)/0.7 (40°C)
Density @ 20°C	1.003 g/mL	1.005 g/mL

   Lastly, please note that the profile summarized on page 6 of the Group B product chemistry study was transcribed incorrectly from Appendix A: Protocol (page 16 of 25), which stated that there is [redacted] in the product. Note that this profile is general in nature and is based on the chemistry of the production process not an analytical result. The Certificate of Conformance (page 25 of 25) should be relied upon for the percent of active ingredient (0.69% FAC = 0.51% HOCl).

2. As per the cover letter dated 08/27/2015, the chemical equation provided in section Chemistry evaluates by-product [redacted] that was not found under Preliminary Analysis and is not mentioned in Discussion of Formation of Impurities.

Manufacturing process information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Registrant response: Please note that the cover letter discussion that describes the use of [redacted]

3. As per the current CSF, it looks like the product is created by [redacted] with the active ingredient that is not in compliance with Description of Production Process provided in MRID 49672601.

   This question has been addressed in Question 3, above.

Manufacturing process information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 26, 2016

DP BARCODE: 430258

MRID(s): 496726-05,-06,-08,-09,-10, 498402-02

SUBJECT: ProduceFresh Produce Quality Treatment Solution

REG. NO. OR FILE SYMBOL: 91685-R

DOCUMENT TYPE: Acute Toxicity Review

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
129054	7790-92-3	Hypochlorous Acid

TEST LAB: Product Safety Labs

SUBMITTER: Puricore, Inc

GUIDELINE(s): 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600.

COMMODITIES: N/A

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** 10/4/2016

COMMENT: This product is for food use

BY
10/4/16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 26, 2016

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No. 91685-R
Product Name: ProduceFresh Produce Quality Treatment Solution
DP Barcode: 430258

TO: Demson Fuller / Srinivas Gowda
PM Team # 32
Risk Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Puricore, Inc
Action code: (A460) New use product
Due out date: October 1, 2016

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Hypochlorous Acid	0.45
Other Ingredient(s)	99.55
TOTAL	100.00

BACKGROUND:

The registrant is submitting 6 acute toxicity studies to support the registration of the subject product, ProduceFresh Produce Quality Treatment Solution, EPA Reg. No. **91685-R**. MRID's are as follows: 496726-05 (81-1), 496726-06 (81-2), 498402-02 (81-3), 496726-08 (81-4), 496726-09 (81-5) and 496726-10 (81-6). The studies were conducted by Product Safety Labs. The test material used in the studies 81-1, 81-2, 81-3…81-6 was the subject product. The test material used in acute inhalation study (81-3) was ProduceFresh Produce Quality Treatment Solution (0.54% Hypochlorous Acid, 0.72% FAC). The product is aimed to reduce bacterial pathogens on processed fruit and vegetable surfaces.

The data package included:

1. Cover letter from Registrant to EPA, dated 02/23/2016.
2. Application for Pesticide, Form 8570-1, dated 02/23/16.
3. Basic Confidential Statements of Formula (CSF), dated 02/23/2016.
4. MRIDs as listed on the front page.
5. Label, dated 08/27/2015.
6. Transmittal document, dated 2/23/2016.
7. Data Matrix, dated 2/23/2016.

FINDINGS:

1. The acute toxicity studies cited are found to be acceptable.
2. The acute toxicity profile for EPA Reg. No. **91685-R** is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	49672605	IV	Acceptable
Acute Dermal Toxicity	49672606	IV	Acceptable
Acute Inhalation Toxicity	49840202	IV	Acceptable
Primary Eye Irritation	49672608	IV	Acceptable
Primary Dermal Irritation	49672609	III	Acceptable
Dermal Sensitization	49672610	*Not* a sensitizer	Acceptable

CONCLUSION:

The acute toxicity requirements have been satisfied for the subject product EPA Reg. No. 91685-R.

LABELING:

ID #: EPA Reg. No.: 91685-R / ProduceFresh Produce Quality Treatment Solution

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Avoid contact with skin or clothing. Wash throughly with soap and water after handing and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact [insert phone number 1-800-xxx-xxxx] for emergency medical treatment information.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OCSPP 870.1100)

Product Manager: D. Fuller
MRID No.: 49672605

CTT Reviewer: B. Yurchak
Reviewer: D. Fefee
Study Completion Date: 2/25/2015
Project No.: 40013

Testing Laboratory: Product Safety Labs (Dayton, New Jersey)
Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: PuriCore Produce Concentrate
Dose level: 5000 mg/kg

Animals: Rat, Sprague-Dawley-derived, albino strain
Sex: 3 Females
Age: 9-10 weeks
Weight: 184-189 grams
Source: SAGE® Labs

Method: Limit Test (OECD 425)

Summary:

1. **Estimated LD_{50}:** >5000 mg/kg
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from OECD 425: None noted.

Results:

Gavage administration of the undiluted test substance to fasted animals in accordance with a limit test under OECD 425 did not result in mortality. [See table below.] Following dose administration on day 0, one animal exhibited reduced fecal volume on days 1-2. No other abnormal clinical signs were observed. All three animals gained weight during both weeks of the study and were free of abnormal gross findings at necropsy.

(Continued on next page)

Reported Mortality

Dosing Sequence	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	5000	O	O
2[a]	5000	O	O
3[a]	5000	O	O

O = Survival; X = Death

[a] Upon survival of the first animal dosed, two additional animals were dosed simultaneously.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OCSPP 870.1200)

Product Manager: D. Fuller
MRID No.: 49672606

CTT Reviewer: B. Yurchak
Reviewer: D. Fefee
Study Completion Date: 2/25/2015
Project No.: 40014

Testing Laboratory: Product Safety Labs (Dayton, New Jersey)
Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: PuriCore Produce Concentrate
Dose level: 5000 mg/kg

Animals: Rat, Sprague-Dawley-derived, albino strain
Sex: 5 Males and 5 Females
Age: 9-10 weeks
Weight: Males: 290-341 grams; Females: 181-233 grams
Source: SAGE® Labs

Summary:

1. **Estimated LD_{50}:** >5000 mg/kg
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from Guideline 870.1200 and other comments: The study used a 2 inch x 3 inch (38.7 cm^2) application site for all of the rats. This area was most likely smaller than 10% of the total body surface area of the heaviest female rat and all of the male rats. [Body surface area of rats (in cm^2) can be estimated as 10.5 x (weight in grams)$^{2/3}$, which would give a range of 397.6-512.5 cm^2 for the total body surface area of these animals (or 39.8-51.3 cm^2 for the minimum sizes of their application sites).]

Results:

The mortality outcomes are provided in the table below. A 24-hour dermal exposure to the undiluted test substance applied to previously clipped skin (~2 inches by 3 inches) at 5000 mg/kg did not result in mortality during the 14-day observation period. There were no abnormal systemic clinical signs. Local effects were noted on the dose sites of three females; these consisted of erythema on day 1 or days 1-2, followed by desquamation that resolved by day 7. One female lost weight during the first week of the study but gained enough weight during the second week to have a net gain for the study duration. The remaining animals gained weight during both weeks of the study. There were no abnormal gross necropsy findings.

(Continued on next page)

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Combined
5000	0 / 5	0 / 5	0 / 10

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OCSPP 870.1300)

Product Manager: D. Fuller
MRID No.: 49840202

CTT Reviewer: B. Yurchak
Study Completion Date: 2/19/2016
Project No.: 42666

Testing Laboratory: Product Safety Labs (Dayton, New Jersey)
Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: ProduceFresh Produce Quality Treatment Solution (0.54% Hypochlorous Acid, 0.72% FAC), clear liquid
Concentrations: Chamber: 2.51 mg/L (gravimetrically determined)
Nominal: 4.73 mg/L
Chamber Type: Nose-Only

Animals: Rat, Sprague-Dawley-derived, albino strain
Sex: 5 Males and 5 Females
Age: Young adult (9-10 weeks)
Weight: Males: 295-324 g; Females: 177-220 g
Source: SAGE Labs

Method: Limit Test (OPP 81-3)

Summary:

1. **LC_{50}:** > 2.51 mg/L (gravimetrically determined)
2. **Mean MMAD:** 2.63 µm with GSD 2.55
3. **Toxicity Category:** IV
4. **Classification:** Acceptable

Deviations from Guideline 870.1300 and other comments: The relative humidity interval in the chamber during exposures was 7-13%, and it is lower than the 30-70% range specified in OCSPP 870.1300.

Results:

There was no mortality following a four-hour inhalation exposure to a mean gravimetric concentration of 2.51 mg/L of the undiluted test item (Limit Test).

All animals appeared normal during exposure and throughout the observation period and gained weight during the study. All animals were normal at necropsy.

(Continued on next page)

Reported Mortality

Exposure Concentration (mg/L)	Number dead / Number tested		
	Males	Females	Combined
2.51	0 / 5	0 / 5	0 / 10

Chamber Atmosphere

Mean Exposure Conc. (mg/L)	MMAD (µm)	GSD
2.51	2.45	2.42
2.51	2.81	2.67
Average	2.63	2.55

Chamber Environment

Exposure Level (mg/L)	2.51
Chamber Volume (L)	28
Total Airflow Rate (Lpm)	26.0
Temperature (°C)	20-21
Relative Humidity (%)	7-13

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OCSPP 870.2400)

Product Manager: D. Fuller
MRID No.: 49672608

CTT Reviewer: B. Yurchak
Reviewer: D. Fefee
Study Completion Date: 2/25/2015
Project No.: 40015

Testing Laboratory: Product Safety Labs (Dayton, New Jersey)
Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: PuriCore Produce Concentrate
Dosage: 0.1 mL

Species: Rabbit, New Zealand albino strain
Sex: 3 Females
Age: 10 weeks
Weight: 2.587-2.804 kg
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Deviations from Guideline 870.2400: None

Results:

The table below provides the results ("positive" irritation) following instillation of 0.1 mL of the undiluted test material into the right eye of three rabbits. Note: prior to instillation and at appropriate intervals thereafter, the animals were given buprenorphine (0.1 mg/kg), and both the treated and control eyes of each animal were topically anesthetized with 2-3 drops of 0.5% Tetracaine Hydrochloride Ophthalmic Solution. There were no observations of corneal opacity or iritis in any treated eye at any time point. At one hour post instillation, all three treated eyes had conjunctival redness (score=1), and one eye had discharge (score=1). Twenty-four hours post instillation, one treated eye had conjunctival redness. All eyes were clear of findings at 48 and 72 hours post instillation. The maximum mean total score was 2.7, at 1 hour post instillation, making the test material minimally irritating (Kay and Calandra).

There were no deaths or abnormal systemic clinical signs, and all of the animals maintained appropriate body weights during the study.

(Continued on next page)

Results

Observations	Number "Positive" / Number Tested			
	Time After Instillation			
	1 hr	24 hrs	48 hrs	72 hrs
Corneal Opacity	0 / 3	0 / 3	0 / 3	0 / 3
Iritis	0 / 3	0 / 3	0 / 3	0 / 3
Conjunctivae				
Redness *	0 / 3	0 / 3	0 / 3	0 / 3
Chemosis *	0 / 3	0 / 3	0 / 3	0 / 3
Discharge**	0 / 3	0 / 3	0 / 3	0 / 3
Severity of Irritation: Mean Total Score	2.7	0.7	0.0	0.0

* Score of 2 or more required to be considered "positive."

** Not considered a positive irritation effect; however, scores of 2 or greater are noted here for completeness.

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OCSPP 870.2500)

Product Manager: D. Fuller
MRID No.: 49672609

CTT Reviewer: B. Yurchak
Reviewer: D. Fefee
Study Completion Date: 2/25/2015
Projeet No.: 40016

Testing Laboratory: Product Safety Labs (Dayton, New Jersey)
Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: PuriCore Produce Concentrate
Dosage: 0.5 mL

Animals: Rabbit, New Zealand albino strain
Sex: 3 Females
Age: 10 weeks
Weight: 2.615-2.722 kg
Souree: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Deviations from Guideline 870.2500: None noted.

Results:

The table below provides the results (individual Draize scores) from four-hour dermal exposures of three rabbits to 0.5 mL of the undiluted test material applied to intact clipped application sites measuring 6 cm^2. From 30-60 minutes through 48 hours after patch removal, all three treated sites exhibited very slight or well-defined erythema and very slight or slight edema; thereafter the incidence and/or severity of these findings decreased. The erythema and edema resolved by 7 days after patch removal (the day on which the study was ended), at which time desquamation was present on two of the application sites. The Primary Irritation Index was 2.92, making the test material a moderate irritant (U.S. EPA, 1988).

There were no deaths or abnormal systemic clinical signs, and all of the animals gained weight during the study.

(Continued on next page)

Individual Dermal Irritation Scores following the four-hour exposure

Animal No.	Sex	Erythema / Edema				
		Time After Patch Removal				
		30-60 minutes	24 hours	48 hours	72 hours	7 days
3501	F	1 / 1	2 / 1	2 / 1	1 / 0	0 / 0[1]
3502	F	2 / 2	2 / 2	2 / 1	2 / 1	0 / 0[1]
3503	F	2 / 2	2 / 1	2 / 1	1 / 1	0 / 0

[1] Desquamation at dose site.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (OCSPP 870.2600)

Product Manager: D. Fuller
MRID No.: 49672610

CTT Reviewer: B. Yurchak
Reviewer: D. Fefee
Study Completion Date: 2/25/2015
Project No.: 40017

Testing Laboratory: Product Safety Labs (Dayton, New Jersey)
Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: PuriCore Produce Concentrate
Induction: 0.4 mL of the undiluted test item
Challenge: 0.4 mL of a 50% w/w mixture of the test item with distilled water

Animals: Guinea pig, Hartley albino strain
Test group: 20 Males
Naive control: 10 Males
Preliminary test: 4 Males
Age: "Young adult" (exaet age not specified)
Weight: 342-407 grams (test group and naïve controls)
Source: Elm Hill Breeding Labs

Historical Positive Control Study: ≥95% alpha-Hexylcinnamaldehyde (HCA)
Guinea pig, Hartley albino; 19 males
Induction: 0.4 mL of undiluted HCA
Challenge: 0.4 mL of undiluted HCA
Conducted 10/14/2014-11/20/2014 (within 6 months of the current study)

Method: Buehler

Summary:

1. Under the conditions of this study, PuriCore Produce Concentrate was *not* a sensitizer.
2. **Classification:** Acceptable

Deviations from Guideline 870.2600: The ages of the animals were not provided.

Procedure Highlights:

- The materials were applied to clipped skin using a 25-mm Hill Top Chamber;
- Exposure periods: 6 hours;
- Inductions: once/week for three weeks (left side); Challenge: 27 days after first dose (right side).

Results:

The results are given in the tables below. Following the first induction, very faint, usually non-confluent erythema or faint, usually confluent erythema (scores=0.5-1) was noted on 19 and 16

animals, at 24 and 48 hours, respectively. Following the second and third inductions, very faint, usually non-confluent erythema or faint, usually confluent erythema (scores=0.5-1) was noted on 18-20 animals at 24 hours, with very faint erythema (score=0.5) seen on 7-12 animals at 48 hours. Following challenge, there were no positive reactions. Very faint (usually non-confluent) erythema was noted on 6/20 treated animals at 24 hours, only, and no erythema was seen on naïve controls at either time point.

All of the animals gained weight during the study. Clinical signs were not reported.

Results of the historical positive control study were appropriate. Following the first induction, there were no skin reactions. Following the second induction, 8/10 and 3/10 animals had very faint, usually non-confluent erythema at 24 and 48 hours, respectively. Following the third induction, 8/10 and 7/10 animals had very faint, usually non-confluent or faint, usually confluent erythema at 24 and 48 hours, respectively. Following challenge, positive responses (score=1) were seen on 7/10 and 4/10 treated animals at 24 and 48 hours, respectively, with three animals showing a positive response across both time points. Very faint, usually non-confluent erythema was seen on 3/10 and 6/10 treated animals at 24 and 48 hours, respectively, and on 2/5 naïve controls at 24 hours, only.

Response Indices - Erythema at Challenge - PuriCore Produce Concentrate

Group	Incidence of Positive Response[1]		Severity[2]	
	24 Hrs	48 Hrs	24 Hrs	48 Hrs
Test Group	0 / 20	0 / 20	0.15	0.00
Naïve Control Group	0 / 10	0 / 10	0.00	0.00

[1] Number of erythema scores greater than 0.5 per number of animals evaluated.
[2] Sum of the erythema scores divided by the number of animals evaluated.

(Continued on next page)

Skin Reaction Scores (Erythema) – PuriCore Produce Concentrate

		Induction						Challenge	
		1		2		3			
Hours after dose		**24[1]**	**48[1]**	**24[1]**	**48[1]**	**24[1]**	**48[1]**	**24**	**48**
Animal	**Sex**								
Test Group									
3601	M	0.5	0	0.5	0.5	0.5	0	0.5	0
3602	M	0.5	0.5	0.5	0	0.5	0	0	0
3603	M	0.5	0.5	0.5	0	0.5	0.5	0	0
3604	M	1	0.5	0.5	0.5	0.5	0	0	0
3605	M	0.5	0.5	0.5	0	0.5	0	0	0
3606	M	1	0.5	1	0.5	0.5	0	0	0
3607	M	1	0.5	0.5	0	0.5	0	0	0
3608	M	0.5	0.5	0.5	0.5	0.5	0.5	0	0
3609	M	0.5	0.5	0.5	0	0.5	0.5	0.5	0
3610	M	0.5	0.5	1	0.5	0.5	0	0	0
3611	M	0.5	0	1	0	0.5	0	0.5	0
3612	M	1	1	1	0.5	0.5	0.5	0.5	0
3613	M	1	1	0.5	0.5	1	0.5	0.5	0
3614	M	0.5	0.5	0.5	0.5	0.5	0	0	0
3615	M	0.5	0.5	0.5	0	0	0	0.5	0
3616	M	0.5	0.5	0.5	0.5	0.5	0	0	0
3617	M	0	0	1	0.5	0.5	0.5	0	0
3618	M	0.5	0	0.5	0	0	0	0	0
3619	M	0.5	0.5	0.5	0.5	0.5	0.5	0	0
3620	M	0.5	0.5	0.5	0.5	0.5	0	0	0
Naïve Control Group									
3621	M	--	--	--	--	--	--	0	0
3622	M	--	--	--	--	--	--	0	0
3623	M	--	--	--	--	--	--	0	0
3624	M	--	--	--	--	--	--	0	0
3625	M	--	--	--	--	--	--	0	0
3626	M	--	--	--	--	--	--	0	0
3627	M	--	--	--	--	--	--	0	0
3628	M	--	--	--	--	--	--	0	0
3629	M	--	--	--	--	--	--	0	0
3630	M	--	--	--	--	--	--	0	0

[1] Light yellow staining noted at all of the dose sites.

2/5/16

Decision #: 508635
DP #: (430258)
PRIA
Parent DP #:
Submission #: 973503
E-Sub #: 8299

DATA PACKAGE BEAN SHEET

Date: 11-Jul-2016

* * * Registration Information * * *

Registration: 91685-R - ProduceFresh Produce Quality Treatment Solution

Company: 91685 - PURICORE INC.

Risk Manager: RM 32 - Demson Fuller - (703) 308-8062 Room# PY1 S-8834

Risk Manager Reviewer: Srinivas Gowda SGOWDA

Sent Date: _____ PRIA Due Date: 13-Feb-2017 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A460) NEW USE;NEW FOOD USE;WITH TOLERANCE EXEMPTION;

Ingredients: 129054, Hypochlorous Acid(.45%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 20-Nov-2015 Due Back: _____

DP Ingredient: 129054, Hypochlorous Acid

DP Title: Acute Toxicity

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

Assigned To		Date In	Date Out		
Organization:	AD / PSB	04-Feb-2016		Last Possible Science Due Date:	01-Oct-2016
Team Name:	CTT	04-Feb-2016		Science Due Date:	
Reviewer Name:	Yurchak, Boris	05-Feb-2016		Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

This is a PRIA action. The Technical Screen ends on 2/9/16.

Please review the Acute Toxicity data in support of this application. Data and other information to support this application can be found on documentum.

If you have any questions, please touch base with Srini Gowda. Thanks.
Demson

AT

to chair 7/11/16

DP#: (430258) *** Studies Sent for Review *** Decision#: (508635)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49672605		Lowe, C. (2015) PuriCore Produce Concentrate: Acute Oral Toxicity - Up-And-Down Procedure in Rats. Project Number: 40013, P320/UDP, 40012. Unpublished study prepared by Product Safety Laboratories. 28p.	870.1100/Acute Oral Toxicity	Pass (10-Sep-2015)
49672606		Lowe, C. (2015) PuriCore Produce Concentrate: Acute Dermal Toxicity in Rats. Project Number: 40014, P322/RAT, 40012. Unpublished study prepared by Product Safety Laboratories. 27p.	870.1200/Acute dermal toxicity	Pass (10-Sep-2015)
49672607		Solomon, E. (2014) Acute Inhalation Toxicity Waiver Request for ProduceFresh(TM). Project Number: PURICORE/32014. Unpublished study prepared by Puricore Inc. 9p.	870.1300/Acute inhalation toxicity	Pass (10-Sep-2015)
49672608		Lowe, C. (2015) PuriCore Produce Concentrate: Primary Eye Irritation in Rabbits. Project Number: 40015, P324, 40012. Unpublished study prepared by Product Safety Laboratories. 31p.	870.2400/Acute eye irritation	Pass (10-Sep-2015)
49672609		Lowe, C. (2015) PuriCore Produce Concentrate: Primary Skin Irritation in Rabbits. Project Number: 40016, P326, 40012. Unpublished study prepared by Product Safety Laboratories. 31p.	870.2500/Acute dermal irritation	Pass (10-Sep-2015)
49672610		Lowe, C. (2015) PuriCore Produce Concentrate: Dermal Sensitization Test in Guinea Pigs - Buehler Method. Project Number: 40017, P328, 40012. Unpublished study prepared by Product Safety Laboratories. 38p.	870.2600/Skin sensitization	Pass (10-Sep-2015)

FORM FOR CTT CONTRACTOR DATA PACKAGE

DP#: 430258 **CTT Reviewer:** B. Yurchak

☑ **Bean sheet included**

Data to be reviewed — *exclude* waiver requests and previously reviewed data:

MRID	Short Descriptor
49672605	870.1100 Acute oral toxicity
49672606	870.1200 Acute dermal toxicity
N/A	870.1300 Acute inhalation toxicity
49672608	870.2400 Acute eye irritation
49672609	870.2500 Acute dermal irritation
49672610	870.2600 Skin Sensitization

If *No* E-Sub#:

- ☐ Transmittal Doc if present (Product Chemistry only)
- ☐ Letter (Product Chemistry only)
- ☐ Proposed label (Product Chemistry only)
- ☐ Proposed CSF (Product Chemistry only)

Product Chemistry:

- ☐ Previous review (if applicable)
- ☐ Last accepted CSF (if applicable)
- ☐ Last reviewed CSF (if applicable)

Comments (if any):

AT Review for EPA Reg. No. 91685-R, ProduceFresh Produce Quality treatment Solution. Please, check carefully the actual dose values in acute oral and acute dermal studies.

7/11/16

Exponent

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

February 23, 2016

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: **Srinivas Gowda, Reviewer/Risk Manager**

Subject: **Response to Technical Screen 10-Day Deficiency Letter**
(Decision No. 508635)
ProduceFresh® Produce Quality Treatment Solution
EPA File Symbol: 91685-R

Dear Mr. Fuller:

On behalf of our client, Puricore Inc. (508 Lapp Road, Malvern, PA 19355, EPA Company Number 91685), Exponent is responding to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

In response to the Agency's letter, Puricore Inc. is providing additional information for each deficiency identified in order to continue the review of this pending application. Responses to each of the efficacy, product chemistry, toxicology and dietary risk assessment technical screen deficiencies listed in the Agency's letter dated February 9, 2016, are enclosed.

Please note that the information in this letter is considered ***Confidential Business Information*** and must not be disclosed to any party outside of EPA. If you have any questions regarding this submission, please contact me at 202-772-4919 or ncowen@exponent.com.

Sincerely,

Nicola D. Cowen, M.Sc.
Authorized Representative of
Puricore Inc.

Enclosures

cc: Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
James B. Messina, Exponent

Claimed confidential by submitter

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: **91685-R**
2. EPA Product Manager: **Demson Fuller**
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): **Puricore Inc. / ProduceFresh® Produce Quality Treatment Solution**
5. PM# **32**
5. Name and Address of Applicant *(Include ZIP Code)*: **Puricore Inc. 508 Lapp Road Malvern, PA 19355**
☐ *Check if this is a new address*
6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated XX-XX-XX
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: ☐ Yes* ☒ No
Certification must be submitted

Unit Packaging: ☐ Yes ☒ No
If "Yes" Unit Packaging wgt.: **5 gallons** No. per Container: **2 (2.5 gallon containers)**

Water Soluble Packaging: ☐ Yes ☒ No
If "Yes" Package wgt. / No. per Container

2. Type of Container: ☐ Metal ☒ Plastic ☐ Glass ☐ Paper/cardboard ☐ Other (Specify) Plastic Bag

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) Retail Container: **2.5 gallons**
5. Location of Label Directions: ☒ On Labeling ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Other _____ ☒ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ethan Solomon	**Associate Director, Research & Development**	**(484) 321-2724**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature: Ethan B. Solomon
3. Title: **Associate Director, Research & Development**
4. Typed Name: **Ethan Solomon**
5. Date: **February 23, 2016**

ProduceFresh® Produce Quality Treatment Solution

Antimicrobial Fruit and Vegetable Wash

For use in retail establishments and commercial or institutional settings, such as grocery stores, convenience stores, kitchens, and food service operations.

Water additive for pathogen reduction in fruit and vegetable wash or process waters

Controls bacterial pathogens (*Escherichia coli, Salmonella enterica,* and *Listeria monocytogenes*) in hydrating and crisping water for fruits and vegetables

Controls spoilage and decay-causing bacteria in fruit and vegetable wash or process waters

Controls spoilage and decay-causing non-public health microorganisms on processed fruit or vegetable surfaces and wash or process waters

Reduces bacterial pathogens on processed fruit and vegetable surfaces

Active Ingredient:	
Hypochlorous Acid*	0.45%
Inert Ingredients	99.55%
Total	100.00%

*Contains 6000 ppm (0.6%) Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center 1-800-222-1222.	

Manufactured by:
Puricore Inc.
508 Lapp Road
Malvern, PA 19355
Ph: +1.484.321.2700

EPA Reg. No.: 91685-R
EPA Est. No.: 91685-PA-001

Net Contents: _____ gal

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

When used as directed under EPA regulations, ProduceFresh® Produce Quality Treatment Solution will:

- [Reduce] [Kill] 99.999% of *Escherichia coli* O157:H7 (ATCC 43895, 35150, 43890), *Salmonella enterica* (ATCC 10721, 6962, 13311), and *Listeria monocytogenes* (ATCC 49594, 19114, 19116) in [hydrating and crisping water] [and] [wash or process water] for fruits and vegetables
- [Controls] [Kills] spoilage and decay causing non-public health microorganisms present in the wash or process water for fruit and vegetable raw agricultural commodities (RACs)
- Control spoilage and decay causing non-public health bacteria in fruit or vegetable wash or process waters
- Control the growth of spoilage and decay causing non-public health bacteria in wash or process water for fruits and vegetables
- Reduces cross contamination of fruits and vegetables from the wash or process water
- Protects against cross contamination in the produce wash water

To treat the surface of *processed* fruits and vegetables (FDA Regulations):

This product may be used in wash water to reduce the pathogens *Escherichia coli O157:H7* (ATCC 43895, 35150, 43890), *Listeria monocytogenes* (ATCC 49594, 19114, 19116), and *Salmonella enterica* (ATCC 10721, 6962, 13311) on the surface of processed fruits and vegetables introduced during handling or processing

- ProduceFresh® Produce Quality Treatment Solution will control the growth of spoilage and decay-causing non-public health microorganisms on processed fruits and vegetables
- Reduce the level of pathogens (*Eschericia coli O157:H7, Listeria monocytogenes, Salmonella enterica*) on the surfaces of processed fruits and vegetables
- Protects against cross contamination of pathogens and spoilage organisms
- Reduces surface residues of organic matter and bacteria

- Reduces the potential for cross contamination and increases the freshness of store-prepared [whole] [and] [cut] fruit and vegetable programs

This use must comply with all applicable FDA regulations, including, but not limited to 21 CFR 173.405, 21 CFR 184.1061, and 21 CFR 170.3.

Use Instructions:

1) Add ProduceFresh® Produce Quality Treatment Solution into processing sink using nozzle connected to the wall-mount dilution system. The wall-mounted diluter provides a solution of ProduceFresh® Produce Quality Treatment Solution containing approximately 30 - 60 parts per million (ppm) of free available chlorine (FAC).

2) Place desired fruits or vegetables (cut or whole) into sink containing ProduceFresh® Produce Quality Treatment Solution. Soak for a minimum of 90 seconds. Remove produce from the solution and set aside to drain.

3) Alternatively, ProduceFresh® Produce Quality Treatment Solution may be introduced onto fruits and vegetables (cut or whole) by rinsing or spraying the solution for a minimum of 90 seconds onto the produce using the supplied nozzle and allowing the solution to drain.

4) The ProduceFresh® Produce Quality Treatment Solution treatment process is continued until all produce requiring treatment (hydration or crisping) is complete.

5) Produce may be used for display or consumed after 10 minutes of draining. No rinse is required.

Use Controls:

- The concentration of free available chlorine (FAC) shall range from 30 - 60 ppm. If the concentration of the solution falls below 30 ppm, the sink is drained and re-filled with fresh ProduceFresh® Produce Quality Treatment Solution using the wall-mount dilution system.

- Test strips are supplied to insure that the FAC of the treatment solution is maintained above 30 ppm. Use a test strip to ensure the treatment solution is above 30 ppm prior to use.

[To Clean and Deodorize]

[Misting Lines:]

- [Can be used in misting lines to keep them clean and free of odor-causing bacteria]
- [Maintains the cleanliness and freshness of water used to mist fresh produce]
- [Maintains the cleanliness of lines used to mist fresh produce]
- [Cleans spray nozzles to improve coverage of produce displayed at retail]

Alternate Brand Name:
ProduceFresh® Antimicrobal Produce Wash

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal, or cleaning of equipment.

Pesticide Storage: Store the product upright and away from sunlight. Keep container tightly closed and store in a cool, well-ventilated area.

Pesticide Disposal: Wastes from this use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

Batch Code XXXXXXX

Exponent

Exponent
1150 Connecticut Ave. NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

September 28, 2015

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk (REGFEE)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: **Reclassification of PRIA Codes for the Pending Registration Applications: FloraFresh® Floral Quality Care Solution (EPA File Symbol 91685-E); Product ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R)**

Dear Demson,

Thank you for your call on September 22, 2015, in which you noted EPA proposes to reclassify the PRIA Codes for the pending product applications FloraFresh® Floral Quality Care Solution (EPA File Symbol 91685-E) and ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol 91685-R).

FloraFresh® Floral Quality Care Solution (EPA File Symbol 91685-E)

Based on this conversation, it is our understanding that the Antimicrobials Division (AD) may transfer the pending FloraFresh® Floral Quality Care Solution product application to the Registration Division (RD). The argument presented, is that no public health pest claims are being made on the label. Puricore disagrees with the EPA's position to move this application to RD, because this product meets the definition of an antimicrobial as presented on the Agency website:

> "An antimicrobial pesticide is intended to disinfect, sanitize, *reduce*, or mitigate growth or development of microbiological organisms or protect inanimate objects, industrial processes or systems, surfaces, *water*, or other chemical substances from contamination, fouling, or deterioration caused by *bacteria*, viruses, fungi, protozoa, algae, or *slime*."
>
> **Italics added to denote claims made on the FloraFresh® Floral Quality Care Solution label.*

FloraFresh is intended to reduce bacteria (albeit non-public health) in the water added to buckets in which flowers are stored. Puricore is not making claims to treat the flowers themselves, but rather the water. Some of the proposed label claims on the FloraFresh® Floral Quality Care Solution product label include:

- Reduces non-public health microorganisms
- Prevents slime and biofilm in the water
- Effective against Pseudomonas and Enterobacter (non-public health) bacteria
- Antimicrobial properties
- The proposed alternate brand names include "Antimicrobial"

Additionally, Puricore met with EPA in 2014 to specifically discuss the potential label claims for a non-regulated and a regulated product for this specific use. At that time, the Agency said it required the product to be registered if the label made some of the claims proposed above.

Further, the active ingredient in this product is identified as having antimicrobial properties and has historically been handled by the EPA's Antimicrobial Division. All of the current registrations for hypochlorous acid are handled within AD as determined by a search of the NPIRS database. The Antimicrobials Division is best equipped to review this product based on their extensive experience with the active ingredient, knowledge of this type of use pattern, and the need for review of the submitted supporting efficacy data. Therefore, we believe that this product is intended for use as an antimicrobial and should be reviewed by AD under PRIA code A540.

ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol 91685-R)

EPA stated in our recent discussion that it proposes to reclassify the PRIA code A540 for ProduceFresh® Produce Quality Treatment Solution from a "new end-use product" to a "new use" application, presumably PRIA Code A460. This topic has been discussed between Puricore and EPA several times. We would like the Agency to consider the following discussion before making a decision to reclassify the PRIA Code for ProduceFresh® Produce Quality Treatment Solution.

Puricore's proposed ProduceFresh® Produce Quality Treatment Solution is regulated by the EPA as a pesticide and by the FDA as a food contact substance. The EPA regulated pesticidal claims for this product are limited to its antimicrobial efficacy to kill pathogens in wash or process waters. The FDA maintains jurisdiction over ProduceFresh® Produce Quality Treatment Solution as it relates to surface contact with the fresh and fresh-cut fruits and vegetables. Through the established Food Contact Substance Notification (FCN) #1470 (FDA Final Letter attached), the FDA has evaluated the use of ProduceFresh® for safety when coming into contact with fresh and fresh-cut fruits and vegetables, and compliance with Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Therefore, a safety determination through a tolerance or tolerance exemption under 40 CFR is duplicative.

Puricore has reviewed the EPA regulatory status of another EPA registered product with identical uses for wash and process waters and fruits and vegetables: Antimicrobial Fruit and Vegetable Treatment (EPA Reg. No. 1677-234, Ecolab). The two active ingredients in this product are Lactic Acid and Dodecylbenzenesulfonic acid, sodium salt. A review of the current tolerance exemptions listed in 40 CFR for these two active ingredients shows that the Agency has not required a tolerance exemption for either active ingredient for this use. There are exemptions from tolerance in place for lactic acid; however, these exemptions are not relevant to the fruit and vegetable wash use. The EPA's Registration Review Final Work Plan for Alkylbenzene Sulfonates (September 2013, attached) indicates that for dodecylbenzenesulfonic acid, sodium salt, the regulations relevant to tolerances for the fruit and vegetable wash use have been established via the FDA (21 CFR 173.315) and that there are no EPA tolerance exemptions for this active ingredient for the fruit and vegetable wash.

As shown on the product label for Puricore's ProduceFresh® Produce Quality Treatment Solution and Ecolab's Antimicrobial Fruit and Vegetable Treatment, there are claims specifically related to the EPA antimicrobial use in wash and process water and claims related to the FDA use as a food contact substance on fresh and fresh-cut fruits and vegetables. These label claim distinctions clearly define that EPA has jurisdiction to regulate the use of this product as an antimicrobial in the treated water while FDA's jurisdiction is the regulation of the contact of the antimicrobial product with the food items, which is supported by the effective food contact notification.

Based on the EPA and FDA jurisdiction of the uses of this product, the use of hypochlorous acid to treat wash or process waters does not require a tolerance or tolerance exemption under FIFRA.

Puricore requests to schedule a conference call with EPA to discuss the proposed changes to both registration applications discussed above. We can be available to discuss this issue on September 29-30, 2015. Please let us know what day and time work for EPA. I can be reached via telephone at 202-772-4919 or via email at ncowen@exponent.com.

Sincerely,

Nicola Cowen, M.Sc.
Authorized Representative of
Puricore Inc.

Enclosures

cc: Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
Carrie Daniels, Exponent
James Messina, Exponent

FDA Food Contact Substance Notification (FCN) #1470

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: February 23, 2016	**EPA Reg. No./File Symbol: 91685-R**	**Page 2 of 2**
Applicant's/Registrant's Name and Address: **Puricore Inc.** **508 Lapp Road** **Malvern, PA 19355**	**Product Name:** **ProduceFresh® Produce Quality Treatment Solution Containing**	
Ingredients: Hypochlorous acid (CAS# 7790-92-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.7000	pH	49672603	Puricore Inc.	OWN	
830.7100	Viscosity	49672603	Puricore Inc.	OWN	
830.7300	Density/relative density/bulk density	49672603	Puricore Inc.	OWN	
830.7520	Particle size, fiber length, and diameter distribution	49840201	Puricore Inc.	OWN	
§ 158.2230: Toxicology Data Requirements					
870.1100	Acute oral toxicity	49672605	Puricore Inc.	OWN	
870.1200	Acute dermal toxicity	49672606	Puricore Inc.	OWN	
870.1300	Acute inhalation toxicity	49672607 49840202	Puricore Inc.	OWN	
870.2400	Primary eye irritation	49672608	Puricore Inc.	OWN	
870.2500	Primary dermal irritation	49672609	Puricore Inc.	OWN	
870.2600	Dermal sensitization	49672610	Puricore Inc.	OWN	
§ 158.2220: Product Performance Data Requirements					
810.2000	*Escherichia coli (ATCC 35150, 43890, and 43895)* *Salmonella Enterica* (ATCC 6962, 10721, and 13311) *Listeria monocytogenes* (ATCC 19114, 19116, and 49594)	49672611	Puricore Inc.	OWN	

Signature: Ethan B. Solomon	**Name and Title:** **Ethan Solomon** **Associate Director,** **Research & Product Development**	**Date:** **Feb 23, 2016**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. ■ Agency Internal Use Copy ☐ Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: February 23, 2016

EPA Reg. No./File Symbol: 91685-R

Applicant's/Registrant's Name and Address: Puricore Inc.
508 Lapp Road
Malvern, PA 19355

Product Name: ProduceFresh® Produce Quality Treatment Solution Containing

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
§ 158.2210: Product Chemistry Data Requirements					
830.1550	Product identity and composition	49672601	Puricore Inc.	OWN	
830.1600	Description of materials used to produce the product	49672601	Puricore Inc.	OWN	
830.1620	Description of production process	49672601	Puricore Inc.	OWN	
830.1650	Description of formulation process	49672601	Puricore Inc.	OWN	
830.1670	Discussion of formation of impurities	49672601	Puricore Inc.	OWN	
830.1700	Preliminary analysis	49672602	Puricore Inc.	OWN	
830.1750	Certified limits	49672601	Puricore Inc.	OWN	
830.1800	Enforcement analytical method	49672601 49672612	Puricore Inc.	OWN	
830.1900	Submittal of samples		Submitted upon request		
Physical and Chemical Properties					
830.6302	Color	49672603	Puricore Inc.	OWN	
830.6303	Physical state	49672603	Puricore Inc.	OWN	
830.6304	Odor	49672603	Puricore Inc.	OWN	
830.6313	Stability (normal/elevated temperatures, metals and ions)	49840201	Puricore Inc.	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	49672603	Puricore Inc.	OWN	
830.6315	Flammability	49840201	Puricore Inc.	OWN	
830.6316	Explodability	49840201	Puricore Inc.	OWN	
830.6317	Storage stability	49672604	Puricore Inc.	OWN	
830.6319	Miscibility	49840201	Puricore Inc.	OWN	
830.6320	Corrosion characteristics	49672604	Puricore Inc.	OWN	
830.6321	Dielectric breakdown voltage	49840201	Puricore Inc.	OWN	

Signature: Ethan B. Solomon

Name and Title: Ethan Solomon
Associate Director,
Research & Product Development

Date: Feb 23, 2016

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

■ Agency Internal Use Copy ❐ Public File Copy

Exponent

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Puricore Inc.
508 Lapp Road
Malvern, PA 19355

CONTACT PERSON (Return to):

Nicola Cowen
Authorized Representative of
Puricore Inc.
Exponent
1150 Connecticut Ave, N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

SUBMITTAL DATE:

February 23, 2016

Volume	Study Title	MRID No.
1	Administrative Materials	49840200
2	Group B Product Chemistry For Puricore Inc.'s ProduceFresh® Produce Quality Treatment Solution; Solomon E., (2016); Study No.: PURICORE022016. EPA Guidelines OCSPP 830.6313; 830.6315; 830.6316; 830.6319; 830.6321; and 830.7520.	49840201
3	ProduceFresh® Produce Quality Treatment Solution: Acute Inhalation Toxicity in Rats; Lowe C., (2016); Study No.: 42666. EPA Guidelines OCSPP 870.1300.	49840202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. No. 91685-R
Product Name: ProduceFresh Produce Quality Treatment Solution
DP Barcode: 430257

TO: Demson Fuller / Srinivas Gowda
PM Team # 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Puricore, Inc
Action code: (A460) New product; non-fast track
Due out date: October 1, 2016

RODUCT FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Hypochlorous Acid*	0.45
Other Ingredients	99.55
Total	100.00

*Contains 6000 ppm (0.6%) Free Available Chlorine (FAC)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

DP BARCODE: 430257

MRID(s): 496726-01,-02,-03,-04, 498402-01

SUBJECT: ProduceFresh Produce Quality Treatment Solution

REG. NO. OR FILE SYMBOL: 91685-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
129054	7790-92-3	Hypochlorous Acid

TEST LAB: N/A

SUBMITTER: Puricore, Inc

GUIDELINE: 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800; 830.6302-830.7300

COMMODITIES: Formulation

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** 10/5/2016

BACKGROUND:

On behalf of the registrant, the Exponent is submitting the completed application for a new registration for the product "ProduceFresh Produce Quality Treatment Solution", EPA Reg. No. **91685-R**. The product is an end-use product of a water-based formulation produced in an integrated system and is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces.

The data package included:

1. Two cover letters from Registrant to EPA, dated 8/27/2015 and 2/23/2016.
2. Application for Pesticide Registration, Form 8570-1, dated 2/23/2016.
3. Two Transmittal Documents, dated 8/26/2015 and 2/23/2016.
4. Data Matrix, dated 2/23/2016.
5. MRIDs, as provided on the front page.
6. Basic CSF, dated 2/23/2016.
7. Label, dated 8/27/2015.

FINDINGS:

1. EPA Reg. No. **91685-R** is an end-use product. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system.

2. The basic CSF is not acceptable due to the following:

   a. The density value placed in box 7 is not supported with study data, see Table for subgroup B, GLN 830.7300.
   b. The active ingredient data shown in columns 13 and 14 without brackets are not in compliance with Product Identity and Composition data provided in MRID 49672601 for the ready to sell and distribution stage of the production process.
   c. Total weight of formulation in box 17 and percentage by weight in the bottom of column 13b are not related to the stage of product production that is ready for sell and distribution.
   d. The certified limits for the active ingredient (0.54% / 0.27%) are not standard for the nominal concentration 0.45% and not supported with the study data provided in MRID 49672601 (0.5% / 0.3%). In tum, the study data are questionable. see Confidential Attachment, GRN 830.1750.
   e. The formulation does not contain an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670.
   f. The formulation is not supported with data provided in section Description of Production/Formulation process of MRID 49672601, see Confidential Attachment, GRNs 830.1620 and 830.1650.

3. Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

4. As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. The requirements of Guideline 830.1620 (Description of Production Process) are not satisfied.

5. Discussion of Formation of Impurities is not supported with chemical equations describing the transformation of starting materials into the final product and by-products and the Preliminary Analysis data. No assessment was conducted to get an amount of mentioned [redacted] The requirements of Guideline 830.1670 are not satisfied.

6. Preliminary analysis study is not acceptable because the analysis did not evaluate an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670. The requirements of Guideline 830.1700 are not satisfied.

7. As per MRID 49672601, the upper certified limit has been fitted equal to production concentration, and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit is based on accelerated storage stability test result that is not acceptable due to the temperature deviation from the standard requirements (see Finding 8 below). Therefore, the requirements of Guideline 830.1750 are not acceptable.

8. As per MRID 49672604 issued 08/21/2015, Storage Stability and Corrosion Characteristics accelerated tests were conducted at temperature 40^0C during 30 days. The condition of the tests is based on old EPA internal instruction issued 3/31/2011 that is no longer valid. The current requirements for an accelerated test are provided in EPA Memorandum dated 11/16/2012. Therefore, the condition of the tests does not satisfy the requirements of Guidelines 830.6317 and 830.6320, respectively.

   In accordance with the Memorandum, for Storage Stability and Corrosion Characteristics, the registrant should provide results for a minimum of 1 year from a GLP compliant storage stability and corrosion characteristics study. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year.

   Or

   Conduct a Storage Stability and Corrosion Characteristics study for 14 days at elevated temperature 54°C±2^0C. The test shall be conducted in compliance with the Good Laboratory Practice standards (GLP) under 40 CFR Part 160.135(b). The concentration(s) of the active ingredient(s) in the product shall be determined at the beginning of the test period and after 14 days, using a validated analytical method. The product should be quantitatively analyzed for active ingredient content and changes in impurities as a result of degradation or packaging deterioration over the test period. Either test should be

conducted with the product in its commercial package or in smaller packages of the same construction and materials.

9. Data reported in MRID #s. 496726-01,-03, and 498402-01 partially satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

10. The Ingredient Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 9-6. However, a note under asterisk mark (*) must be deleted because 4500 ppm of Hypochlorous Acid cannot contain 6000 ppm of FAC. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSION:

The basic CSF, dated 2/23/2016, for EPA Reg. No. 91685-R is not acceptable (Finding 2). The registrant will have satisfied the product chemistry requirements after submission of the corrected basic CSF that is harmonized and supported with study data (Findings 3-5, 7). The impurities that accompanied the production process with a nominal concentration greater than 0.1% must be fully described in section Discussion of formation of impurities (Finding 5) and assessed in Preliminary Analysis (Finding 6) and shown on the CSF. The Storage Stability and Corrosion Characteristics data must be evaluated under current OCSPP requirements (Finding 8).

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	49672601	Y
.1600 Description of Materials Used to Produce the Product	158.325	49672601	N (See Finding 3)
.1620 Description of Production Process	158.330	49672601	N (See Finding 4)
.1650 Discussion of Formulation Process	158.165		N/A
.1670 Discussion of Formation of Impurities	158.167	49672601	N (see Finding 5 and Conf. Attach)
.1700 Preliminary Analysis	158.345	49672602	N (See Finding 6 and Conf. Attach.)
.1750 Certified Limits	158.350	49672601	N (see Finding 7 and Conf. Attach)
.1800 Enforcement Analytical Method	158.355	49672612	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

830.1800. Enforcement Analytical Method

The subject product was analyzed for the active ingredient Hypochlorous Acid using a titration-based analytical procedure based on determination of free available chlorine (FAC).

Equipment:

1. Radiometer Model TIM900 Autotitrator
2. Electrode Pt Electrode, M241Pt2-8

Titrant: 0.1N Sodium Thiosulfate ($Na_2S_2O_3$)
The method is adequate and satisfies the requirements under Guideline 830.1800.

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Colorless to slightly yellow	49672603	Y
.6303 Physical State	Clear liquid	49672603	Y
.6304 Odor	Chlorine-like	49672603	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	This product will not come into contact with metal or metal ions.	49840201	N/A
.6314 Oxidation/Reduction Chemical Incompatibility	Agent / Compatibility: Water – compatible; 10% Monoammonium phosphate solution – compatible; Iron powder – compatible; 10% Potassium permanganate solution – compatible; Kerosene – compatible	49672603	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	49840201	N/A
.6316 Explodability	The product is not potentially explosive.	49840201	N/A
.6317 Storage Stability	Stable for 30 days at T=40°C	49672604	N (See Finding 8)
.6319 Miscibility	The product is not to be mixed with petroleum distillate.	49840201	N/A
.6320 Corrosion Characteristics	Not corrosive after 1 month of storage at T=40°C	49672604	N (See Finding 8)
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	49840201	N/A
.7000 pH	5.44	49672603	Y
	4.0 – 6.0	CSF	
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	1.0 Centistokes @20.0°C; 0.7 Centistokes @40.0°C	49672603	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.005 g/mL @ 20°C	49672603	Y
	1.01 – 1.07 g/mL	CSF	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Confidential Appendix A

830.1550. Product Identity and Composition

EPA Reg. No. 91685-R is an end-use product, containing the active ingredients Hypochlorous Acid, CAS No. 7790-92-3 with a label claim nominal concentration of 0.45%, and other ingredients content of 99.55%. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system. The requirements of Guideline 830.1550 are satisfied.

830.1600. Description of Materials Used to Produce the Product

Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

830.1620. Description of Production Process

As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. Additionally, the Description is not accompanied with chemical equations describing scientifically the production process with evaluation of by-products. The requirements of Guideline 830.1620 are not satisfied.

830.1670. Discussion of Formation of Impurities

Data provided in MRID 49672601 describe the formation of impurities during the production process not based on established chemical theory without providing chemical equations pertained to the current production process. The study only mentioned [redacted] in the product but no data about its amount (concentration) are provided. The requirements of Guideline 830.1670 are not satisfied.

830.1700. Preliminary Analysis

Preliminary Analysis data are provided in MRID 49672602 and are listed in the table below. The study is not acceptable because the analysis did not evaluate [redacted] mentioned in section Discussion of Formation of Impurities of MRID 49672601 as well as other possible by-products.

Manufacturing process information may be entitled to confidential treatment

Summary of Composition			
Test Substance ID	Batch No.	%Hypochlorous acid	% Free Available Chlorine (FAC)
ProduceFresh Produce Quality Treatment Solution	VP-1 032415	0.46	0.62
	VP-2 032415	0.50	0.68
	VP-3 032415	0.42	0.56
	VP-4 032415	0.42	0.57
	VP-5 032415	0.46	0.63

The requirements of Guideline 830.1700 are not satisfied.

830.1750. Certified Limits

As per MRID 49672601, the upper certified limit (0.5%) has been fitted equal to the production concentration and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit (0.3%) is based on the result of accelerated storage stability test that is not acceptable due to a temperature deviation from the standard requirements. Therefore, the requirements of Guideline 830.1750 are not acceptable.

Notes to PM:

1. The substance tested for group B data and described in MRID 49672603 has a higher level of the nominal concentration compared with the same on the CSF and the label (0.65% vs 0.45%). Additionally, the test substance contains an impurity [redacted] that is not shown in the formulation and has not been evaluated during the studies. Thus, the group B data are questionable.

2. As per the cover letter dated 08/27/2015, the chemical equation provided in section Chemistry evaluates by-product [redacted] that was not found under Preliminary Analysis and is not mentioned in Discussion of Formation of Impurities.

3. As per the current CSF, it looks like the product is created by [redacted] with the active ingredient that is not in compliance with Description of Production Process provided in MRID 49672601.

Feb 13th

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

DP BARCODE: 430257

MRID(s): 496726-01,-02,-03,-04, 498402-01

SUBJECT: ProduceFresh Produce Quality Treatment Solution

REG. NO. OR FILE SYMBOL: 91685-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
129054	7790-92-3	Hypochlorous Acid

TEST LAB: N/A

SUBMITTER: Puricore, Inc

GUIDELINE: 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800; 830.6302-830.7300

COMMODITIES: Formulation

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** ___/___/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. No. 91685-R
Product Name: ProduceFresh Produce Quality Treatment Solution
DP Barcode: 430257

TO: Demson Fuller / Srinivas Gowda
PM Team # 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Puricore, Inc
Action code: (A460) New product; non-fast track
Due out date: October 1, 2016

RODUCT FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Hypochlorous Acid*	0.45
Other Ingredients	99.55
Total	100.00

*Contains 6000 ppm (0.6%) Free Available Chlorine (FAC)

BACKGROUND:

On behalf of the registrant, the Exponent is submitting the completed application for a new registration for the product "ProduceFresh Produce Quality Treatment Solution", EPA Reg. No. **91685-R**. The product is an end-use product of a water-based formulation produced in an integrated system and is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces.

The data package included:

1. Two cover letters from Registrant to EPA, dated 8/27/2015 and 2/23/2016.
2. Application for Pesticide Registration, Form 8570-1, dated 2/23/2016.
3. Two Transmittal Documents, dated 8/26/2015 and 2/23/2016.
4. Data Matrix, dated 2/23/2016.
5. MRIDs, as provided on the front page.
6. Basic CSF, dated 2/23/2016.
7. Label, dated 8/27/2015.

FINDINGS:

1. EPA Reg. No. **91685-R** is an end-use product. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system.

2. The basic CSF is not acceptable due to the following:

   a. The density value placed in box 7 is not supported with study data, see Table for subgroup B, GLN 830.7300.
   b. The active ingredient data shown in column 13 and 14 without brackets are pertained not to the ready for sell and distribution stage.
   c. Total weight of formulation in box 17 and percentage by weight in the bottom of column 13b are not related to the stage of product production that is ready for sell and distribution.
   d. The certified limits for the active ingredient (0.54% / 0.27%) are not standard for the nominal concentration 0.45% and not supported with the study data provided in MRID 49672601 (0.5% / 0.3%). In turn, the study data are questionable, see Confidential Attachment, GRN 830.1750.
   e. The formulation does not contain an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670.
   f. The formulation is not supported with data provided in section Description of Production/Formulation process of MRID 49672601, see Confidential Attachment, GRNs 830.1620 and 830.1650.

3. Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

4. As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. The requirements of Guideline 830.1620 (Description of Production Process) are not satisfied.

5. Discussion of Formation of Impurities is not supported with chemical equations describing the transformation of starting materials into the final product and by-products and the Preliminary Analysis data. No assessment was conducted to get an amount of mentioned [redacted] The requirements of Guideline 830.1670 are not satisfied.

6. Preliminary analysis study is not acceptable because the analysis did not evaluate an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670. The requirements of Guideline 830.1700 are not satisfied.

7. As per MRID 49672601, the upper certified limit has been fitted equal to production concentration and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit is based on accelerated storage stability test result that is not acceptable due to a temperature deviation from standard requirements (see Finding 8 below). Therefore, the requirements of Guideline 830.1750 are not acceptable.

8. As per MRID 49672604, Storage Stability and Corrosion Characteristics accelerated tests were conducted at temperature 40^0C during 30 days. Therefore, the conditions of the tests do not satisfy the requirements of Guidelines 830.6317 and 830.6320, respectively.

   For Storage Stability and Corrosion Characteristics, the registrant should provide results for a minimum of 1 year from a GLP compliant storage stability and corrosion characteristics study. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year.
   Or
   Conduct a Storage Stability and Corrosion Characteristics study for 14 days at elevated temperature 54°C±2^0C. The test shall be conducted in compliance with the Good Laboratory Practice standards (GLP) under 40 CFR Part 160.135(b). The concentration(s) of the active ingredient(s) in the product shall be determined at the beginning of the test period and after 14 days, using a validated analytical method. The product should be quantitatively analyzed for active ingredient content and changes in impurities as a result of degradation or packaging deterioration over the test period. Either test should be conducted with the product in its commercial package or in smaller packages of the same construction and materials.

9. Data reported in MRID Nos. 496726-01,-02,-03,-04, and 498402-01 partially satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

10. The Ingredient Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 9-6. However, a note under asterisk mark (*) must be deleted because 4500 ppm of Hypochlorous Acid cannot contain 6000 ppm of FAC. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSION:

The basic CSF, dated 2/23/2016, for EPA Reg. No. 91685-R is not acceptable (Finding 2). The registrant will have satisfied the product chemistry requirements after submission of the corrected basic CSF that is harmonized and supported with studies data (Findings 3-5, 7). The impurities accompanied the production process with nominal concentration greater than 0.1% must be fully described in section Discussion of formation of impurities (Finding 5) and assessed in Preliminary Analysis (Finding 6) and shown on the CSF. The Storage Stability and Corrosion Characteristics data must be evaluated under OCSPP requirements (Finding 8).

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	49672601	Y
.1600 Description of Materials Used to Produce the Product	158.325	49672601	N (See Finding 3)
.1620 Description of Production Process	158.330	49672601	N (See Finding 4)
.1650 Discussion of Formulation Process	158.165		N/A
.1670 Discussion of Formation of Impurities	158.167	49672601	N (see Finding 5 and Conf. Attach)
.1700 Preliminary Analysis	158.345	49672602	N (See Finding 6 and Conf. Attach.)
.1750 Certified Limits	158.350	49672601	N (see Finding 7 and Conf. Attach)
.1800 Enforcement Analytical Method	158.355	49672612	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

830.1800. Enforcement Analytical Method

The subject product was analyzed for the active ingredient Hypochlorous Acid using a titration-based analytical procedure based on determination of free available chlorine (FAC).

Equipment:

1. Radiometer Model TIM900 Autotitrator
2. Electrode Pt Electrode, M241Pt2-8

Titrant: 0.1N Sodium Thiosulfate ($Na_2S_2O_3$)
The method is adequate and satisfies the requirements under Guideline 830.1800.

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Colorless to slightly yellow	49672603	Y
.6303 Physical State	Clear liquid	49672603	Y
.6304 Odor	Chlorine-like	49672603	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	This product will not come into contact with metal or metal ions.	49840201	N/A
.6314 Oxidation/Reduction Chemical Incompatibility	Agent / Compatibility: Water – compatible; 10% Monoammonium phosphate solution – compatible; Iron powder – compatible; 10% Potassium permanganate solution – compatible; Kerosene – compatible	49672603	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	49840201	N/A
.6316 Explodability	The product is not potentially explosive.	49840201	N/A
.6317 Storage Stability	Stable for 30 days at T=40^{0}C	49672604	N (See Finding 6)
.6319 Miscibility	The product is not to be mixed with petroleum distillate.	49840201	N/A
.6320 Corrosion Characteristics	Not corrosive after 1 month of storage at T=40^{0}C	49672604	N (See Finding 6)
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	49840201	N/A
.7000 pH	5.44	49672603	Y
	4.0 – 6.0	CSF	
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	1.0 Centistokes @20.0°C; 0.7 Centistokes @40.0°C	49672603	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.005 g/mL @ 20°C	49672603	Y
	1.01 – 1.07 g/mL	CSF	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Confidential Appendix A

830.1550. Product Identity and Composition

EPA Reg. No. 91685-R is an end-use product, containing the active ingredients Hypochlorous Acid, CAS No. 7790-92-3 with a label claim nominal concentration of 0.45%, and other ingredients content of 99.55%. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system. The requirements of Guideline 830.1550 are satisfied.

830.1600. Description of Materials Used to Produce the Product

Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

830.1620. Description of Production Process

As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. Additionally, the Description is not accompanied with chemical equations describing scientifically the production process. The requirements of Guideline 830.1620 are not satisfied.

830.1670. Discussion of Formation of Impurities

Data provided in MRID 49672601 describe the formation of impurities during the production process not based on established chemical theory without providing chemical equations pertained to the current production process. The study only mentioned [redacted] in the product but no data about its amount (concentration) are provided. The requirements of Guideline 830.1670 are not satisfied.

830.1700. Preliminary Analysis

Preliminary Analysis data are provided in MRID 49672602 and are listed in the table below. The study is not acceptable because the analysis did not evaluate [redacted] mentioned in section Discussion of Formation of Impurities of MRID 49672601.

Summary of Composition			
Test Substance ID	Batch No.	%Hypochlorous acid	% Free Available Chlorine (FAC)
ProduceFresh Produce Quality Treatment Solution	VP-1 032415	0.46	0.62
	VP-2 032415	0.50	0.68
	VP-3 032415	0.42	0.56
	VP-4 032415	0.42	0.57
	VP-5 032415	0.46	0.63

The requirements of Guideline 830.1700 are not satisfied.

830.1750. Certified Limits

As per MRID 49672601, the upper certified limit (0.5%) has been fitted equal to the production concentration and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit (0.3%) is based on the result of accelerated storage stability test that is not acceptable due to a temperature deviation from the standard requirements. Therefore, the requirements of Guideline 830.1750 are not acceptable.

Notes to PM:

1. The substance tested for group B data and described in MRID 49672603 has a higher level of the nominal concentration compared with the same on the CSF and the label (0.65% vs 0.45%). It looks like the FAC is presumed. Additionally, the test substance contains an impurity [redacted] that does not shown in the formulation and has not been evaluated during the studies.

2. As per the cover letter dated 08/27/2015, the chemical equation provided in section Chemistry evaluates by-product [redacted] that is not found under Preliminary Analysis and is not mentioned in Discussion of Formation of Impurities.

3. As per the current CSF, it looks like the product is created by [redacted] with the active ingredient that is not in compliance with Description of Production Process provided in MRID 49672601. It is impossible to explain the presence of [redacted] in the formulation without providing a pre-reaction CSF.

Demson

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. No. 91685-R
Product Name: ProduceFresh Produce Quality Treatment Solution
DP Barcode: 430257

TO: Demson Fuller / Srinivas Gowda
PM Team # 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Puricore, Inc
Action code: (A460) New product; non-fast track
Due out date: October 1, 2016

RODUCT FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Hypochlorous Acid*	0.45
Other Ingredients	99.55
Total	100.00

*Contains 6000 ppm (0.6%) Free Available Chlorine (FAC)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

DP BARCODE: 430257

MRID(s): 496726-01,-02,-03,-04, 498402-01

SUBJECT: ProduceFresh Produce Quality Treatment Solution

REG. NO. OR FILE SYMBOL: 91685-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
129054	7790-92-3	Hypochlorous Acid

TEST LAB: N/A

SUBMITTER: Puricore, Inc

GUIDELINE: 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800; 830.6302-830.7300

COMMODITIES: Formulation

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** ___/___/2016

BACKGROUND:

On behalf of the registrant, the Exponent is submitting the completed application for a new registration for the product "ProduceFresh Produce Quality Treatment Solution", EPA Reg. No. **91685-R**. The product is an end-use product of a water-based formulation produced in an integrated system and is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces.

The data package included:

1. Two cover letters from Registrant to EPA, dated 8/27/2015 and 2/23/2016.
2. Application for Pesticide Registration, Form 8570-1, dated 2/23/2016.
3. Two Transmittal Documents, dated 8/26/2015 and 2/23/2016.
4. Data Matrix, dated 2/23/2016.
5. MRIDs, as provided on the front page.
6. Basic CSF, dated 2/23/2016.
7. Label, dated 8/27/2015.

FINDINGS:

1. EPA Reg. No. **91685-R** is an end-use product. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system.

2. The basic CSF is not acceptable due to the following:

   a. The density value placed in box 7 is not supported with study data, see Table for subgroup B, GLN 830.7300.
   b. The active ingredient data shown in column 13 and 14 without brackets are pertained not to the ready for sell and distribution stage.
   c. Total weight of formulation in box 17 and percentage by weight in the bottom of column 13b are not related to the stage of product production that is ready for sell and distribution.
   d. The certified limits for the active ingredient (0.54% / 0.27%) are not standard for the nominal concentration 0.45% and not supported with the study data provided in MRID 49672601 (0.5% / 0.3%). In turn, the study data are questionable, see Confidential Attachment, GRN 830.1750.
   e. The formulation does not contain an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670.
   f. The formulation is not supported with data provided in section Description of Production/Formulation process of MRID 49672601, see Confidential Attachment, GRNs 830.1620 and 830.1650.

3. Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

4. As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. The requirements of Guideline 830.1620 (Description of Production Process) are not satisfied.

5. Discussion of Formation of Impurities is not supported with chemical equations describing the transformation of starting materials into the final product and by-products and the Preliminary Analysis data. No assessment was conducted to get an amount of mentioned [redacted] The requirements of Guideline 830.1670 are not satisfied.

6. Preliminary analysis study is not acceptable because the analysis did not evaluate an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670. The requirements of Guideline 830.1700 are not satisfied.

7. As per MRID 49672601, the upper certified limit has been fitted equal to production concentration and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit is based on accelerated storage stability test result that is not acceptable due to a temperature deviation from standard requirements (see Finding 8 below). Therefore, the requirements of Guideline 830.1750 are not acceptable.

8. As per MRID 49672604, Storage Stability and Corrosion Characteristics accelerated tests were conducted at temperature 40^0C during 30 days. Therefore, the conditions of the tests do not satisfy the requirements of Guidelines 830.6317 and 830.6320, respectively.

   For Storage Stability and Corrosion Characteristics, the registrant should provide results for a minimum of 1 year from a GLP compliant storage stability and corrosion characteristics study. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year.
   Or
   Conduct a Storage Stability and Corrosion Characteristics study for 14 days at elevated temperature 54°C±2^0C. The test shall be conducted in compliance with the Good Laboratory Practice standards (GLP) under 40 CFR Part 160.135(b). The concentration(s) of the active ingredient(s) in the product shall be determined at the beginning of the test period and after 14 days, using a validated analytical method. The product should be quantitatively analyzed for active ingredient content and changes in impurities as a result of degradation or packaging deterioration over the test period. Either test should be conducted with the product in its commercial package or in smaller packages of the same construction and materials.

9. Data reported in MRID Nos. 496726-01,-02,-03,-04, and 498402-01 partially satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

10. The Ingredient Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 9-6. However, a note under asterisk mark (*) must be deleted because 4500 ppm of Hypochlorous Acid cannot contain 6000 ppm of FAC. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSION:

The basic CSF, dated 2/23/2016, for EPA Reg. No. 91685-R is not acceptable (Finding 2). The registrant will have satisfied the product chemistry requirements after submission of the corrected basic CSF that is harmonized and supported with studies data (Findings 3-5, 7). The impurities accompanied the production process with nominal concentration greater than 0.1% must be fully described in section Discussion of formation of impurities (Finding 5) and assessed in Preliminary Analysis (Finding 6) and shown on the CSF. The Storage Stability and Corrosion Characteristics data must be evaluated under OCSPP requirements (Finding 8).

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	49672601	Y
.1600 Description of Materials Used to Produce the Product	158.325	49672601	N (See Finding 3)
.1620 Description of Production Process	158.330	49672601	N (See Finding 4)
.1650 Discussion of Formulation Process	158.165		N/A
.1670 Discussion of Formation of Impurities	158.167	49672601	N (see Finding 5 and Conf. Attach)
.1700 Preliminary Analysis	158.345	49672602	N (See Finding 6 and Conf. Attach.)
.1750 Certified Limits	158.350	49672601	N (see Finding 7 and Conf. Attach)
.1800 Enforcement Analytical Method	158.355	49672612	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

830.1800. Enforcement Analytical Method

The subject product was analyzed for the active ingredient Hypochlorous Acid using a titration-based analytical procedure based on determination of free available chlorine (FAC).

Equipment:

1. Radiometer Model TIM900 Autotitrator
2. Electrode Pt Electrode, M241Pt2-8

Titrant: 0.1N Sodium Thiosulfate ($Na_2S_2O_3$)
The method is adequate and satisfies the requirements under Guideline 830.1800.

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Colorless to slightly yellow	49672603	Y
.6303 Physical State	Clear liquid	49672603	Y
.6304 Odor	Chlorine-like	49672603	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	This product will not come into contact with metal or metal ions.	49840201	N/A
.6314 Oxidation/Reduction Chemical Incompatibility	Agent / Compatibility: Water – compatible; 10% Monoammonium phosphate solution – compatible; Iron powder – compatible; 10% Potassium permanganate solution – compatible; Kerosene – compatible	49672603	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	49840201	N/A
.6316 Explodability	The product is not potentially explosive.	49840201	N/A
.6317 Storage Stability	Stable for 30 days at T=40^{0}C	49672604	N (See Finding 6)
.6319 Miscibility	The product is not to be mixed with petroleum distillate.	49840201	N/A
.6320 Corrosion Characteristics	Not corrosive after 1 month of storage at T=40^{0}C	49672604	N (See Finding 6)
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	49840201	N/A
.7000 pH	5.44	49672603	Y
	4.0 – 6.0	CSF	
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	1.0 Centistokes @20.0°C; 0.7 Centistokes @40.0°C	49672603	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.005 g/mL @ 20°C	49672603	Y
	1.01 – 1.07 g/mL	CSF	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Confidential Appendix A

830.1550. Product Identity and Composition

EPA Reg. No. 91685-R is an end-use product, containing the active ingredients Hypochlorous Acid, CAS No. 7790-92-3 with a label claim nominal concentration of 0.45%, and other ingredients content of 99.55%. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system. The requirements of Guideline 830.1550 are satisfied.

830.1600. Description of Materials Used to Produce the Product

Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

830.1620. Description of Production Process

As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. Additionally, the Description is not accompanied with chemical equations describing scientifically the production process. The requirements of Guideline 830.1620 are not satisfied.

830.1670. Discussion of Formation of Impurities

Data provided in MRID 49672601 describe the formation of impurities during the production process not based on established chemical theory without providing chemical equations pertained to the current production process. The study only mentioned [redacted] in the product but no data about its amount (concentration) are provided. The requirements of Guideline 830.1670 are not satisfied.

830.1700. Preliminary Analysis

Preliminary Analysis data are provided in MRID 49672602 and are listed in the table below. The study is not acceptable because the analysis did not evaluate [redacted] mentioned in section Discussion of Formation of Impurities of MRID 49672601.

Summary of Composition			
Test Substance ID	Batch No.	%Hypochlorous acid	% Free Available Chlorine (FAC)
ProduceFresh Produce Quality Treatment Solution	VP-1 032415	0.46	0.62
	VP-2 032415	0.50	0.68
	VP-3 032415	0.42	0.56
	VP-4 032415	0.42	0.57
	VP-5 032415	0.46	0.63

The requirements of Guideline 830.1700 are not satisfied.

830.1750. Certified Limits

As per MRID 49672601, the upper certified limit (0.5%) has been fitted equal to the production concentration and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit (0.3%) is based on the result of accelerated storage stability test that is not acceptable due to a temperature deviation from the standard requirements. Therefore, the requirements of Guideline 830.1750 are not acceptable.

Notes to PM:

1. The substance tested for group B data and described in MRID 49672603 has a higher level of the nominal concentration compared with the same on the CSF and the label (0.65% vs 0.45%). It looks like the FAC is presumed. Additionally, the test substance contains an impurity [redacted] that does not shown in the formulation and has not been evaluated during the studies.

2. As per the cover letter dated 08/27/2015, the chemical equation provided in section Chemistry evaluates by-product [redacted] that is not found under Preliminary Analysis and is not mentioned in Discussion of Formation of Impurities.

3. As per the current CSF, it looks like the product is created by [redacted] with the active ingredient that is not in compliance with Description of Production Process provided in MRID 49672601. It is impossible to explain the presence of [redacted] in the formulation without providing a pre-reaction CSF.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

DP BARCODE: 430257

MRID(s): 496726-01,-02,-03,-04, 498402-01

SUBJECT: ProduceFresh Produce Quality Treatment Solution

REG. NO. OR FILE SYMBOL: 91685-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR **End-use Product [X]**

INGREDIENTS:

PC Code(s)	CAS Number(s)	Active Ingredient(s):
129054	7790-92-3	Hypochlorous Acid

Completed and Downloaded
D.Y.

TEST LAB: N/A

SUBMITTER: Puricore, Inc

GUIDELINE: 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800; 830.6302-830.7300

COMMODITIES: Formulation

REVIEWER: Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

APPROVER: Karen P. Hicks **APPROVED DATE:** 10/5/2016

B.Y.
10/6/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Antimicrobial Division

September 22, 2016

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. No. 91685-R
Product Name: ProduceFresh Produce Quality Treatment Solution
DP Barcode: 430257

TO: Demson Fuller / Srinivas Gowda
PM Team # 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

APPLICANT: Puricore, Inc
Action code: (A460) New product; non-fast track
Due out date: October 1, 2016

RODUCT FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Hypochlorous Acid*	0.45
Other Ingredients	99.55
Total	100.00

*Contains 6000 ppm (0.6%) Free Available Chlorine (FAC)

BACKGROUND:

On behalf of the registrant, the Exponent is submitting the completed application for a new registration for the product "ProduceFresh Produce Quality Treatment Solution", EPA Reg. No. **91685-R**. The product is an end-use product of a water-based formulation produced in an integrated system and is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces.

The data package included:

1. Two cover letters from Registrant to EPA, dated 8/27/2015 and 2/23/2016.
2. Application for Pesticide Registration, Form 8570-1, dated 2/23/2016.
3. Two Transmittal Documents, dated 8/26/2015 and 2/23/2016.
4. Data Matrix, dated 2/23/2016.
5. MRIDs, as provided on the front page.
6. Basic CSF, dated 2/23/2016.
7. Label, dated 8/27/2015.

FINDINGS:

1. EPA Reg. No. **91685-R** is an end-use product. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system.

2. The basic CSF is not acceptable due to the following:

   a. The density value placed in box 7 is not supported with study data, see Table for subgroup B, GLN 830.7300.
   b. The active ingredient data shown in columns 13 and 14 without brackets are not in compliance with Product Identity and Composition data provided in MRID 49672601 for the ready to sell and distribution stage of the production process.
   c. Total weight of formulation in box 17 and percentage by weight in the bottom of column 13b are not related to the stage of product production that is ready for sell and distribution.
   d. The certified limits for the active ingredient (0.54% / 0.27%) are not standard for the nominal concentration 0.45% and not supported with the study data provided in MRID 49672601 (0.5% / 0.3%). In turn, the study data are questionable, see Confidential Attachment, GRN 830.1750.
   e. The formulation does not contain an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670.
   f. The formulation is not supported with data provided in section Description of Production/Formulation process of MRID 49672601, see Confidential Attachment, GRNs 830.1620 and 830.1650.

3. Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

4. As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. The requirements of Guideline 830.1620 (Description of Production Process) are not satisfied.

5. Discussion of Formation of Impurities is not supported with chemical equations describing the transformation of starting materials into the final product and by-products and the Preliminary Analysis data. No assessment was conducted to get an amount of mentioned [redacted] The requirements of Guideline 830.1670 are not satisfied.

6. Preliminary analysis study is not acceptable because the analysis did not evaluate an impurity mentioned in section Discussion of Formation of Impurities of MRID 49672601, see Confidential Attachment, GRN 830.1670. The requirements of Guideline 830.1700 are not satisfied.

7. As per MRID 49672601, the upper certified limit has been fitted equal to production concentration, and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit is based on accelerated storage stability test result that is not acceptable due to the temperature deviation from the standard requirements (see Finding 8 below). Therefore, the requirements of Guideline 830.1750 are not acceptable.

8. As per MRID 49672604 issued 08/21/2015, Storage Stability and Corrosion Characteristics accelerated tests were conducted at temperature 40^0C during 30 days. The condition of the tests is based on old EPA internal instruction issued 3/31/2011 that is no longer valid. The current requirements for an accelerated test are provided in EPA Memorandum dated 11/16/2012. Therefore, the condition of the tests does not satisfy the requirements of Guidelines 830.6317 and 830.6320, respectively.

   In accordance with the Memorandum, for Storage Stability and Corrosion Characteristics, the registrant should provide results for a minimum of 1 year from a GLP compliant storage stability and corrosion characteristics study. The concentration of the active ingredients in the product must be determined at the beginning of the test period and every 3 months thereafter for a period of 1 year.
   Or
   Conduct a Storage Stability and Corrosion Characteristics study for 14 days at elevated temperature 54°C±2^0C. The test shall be conducted in compliance with the Good Laboratory Practice standards (GLP) under 40 CFR Part 160.135(b). The concentration(s) of the active ingredient(s) in the product shall be determined at the beginning of the test period and after 14 days, using a validated analytical method. The product should be quantitatively analyzed for active ingredient content and changes in impurities as a result of degradation or packaging deterioration over the test period. Either test should be

conducted with the product in its commercial package or in smaller packages of the same construction and materials.

9. Data reported in MRID #s. 496726-01,-03, and 498402-01 partially satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

10. The Ingredient Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 9-6. However, a note under asterisk mark (*) must be deleted because 4500 ppm of Hypochlorous Acid cannot contain 6000 ppm of FAC. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSION:

The basic CSF, dated 2/23/2016, for EPA Reg. No. 91685-R is not acceptable (Finding 2). The registrant will have satisfied the product chemistry requirements after submission of the corrected basic CSF that is harmonized and supported with study data (Findings 3-5, 7). The impurities that accompanied the production process with a nominal concentration greater than 0.1% must be fully described in section Discussion of formation of impurities (Finding 5) and assessed in Preliminary Analysis (Finding 6) and shown on the CSF. The Storage Stability and Corrosion Characteristics data must be evaluated under current OCSPP requirements (Finding 8).

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	49672601	Y
.1600 Description of Materials Used to Produce the Product	158.325	49672601	N (See Finding 3)
.1620 Description of Production Process	158.330	49672601	N (See Finding 4)
.1650 Discussion of Formulation Process	158.165		N/A
.1670 Discussion of Formation of Impurities	158.167	49672601	N (see Finding 5 and Conf. Attach)
.1700 Preliminary Analysis	158.345	49672602	N (See Finding 6 and Conf. Attach.)
.1750 Certified Limits	158.350	49672601	N (see Finding 7 and Conf. Attach)
.1800 Enforcement Analytical Method	158.355	49672612	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

830.1800. Enforcement Analytical Method

The subject product was analyzed for the active ingredient Hypochlorous Acid using a titration-based analytical procedure based on determination of free available chlorine (FAC).

Equipment:

1. Radiometer Model TIM900 Autotitrator
2. Electrode Pt Electrode, M241Pt2-8

Titrant: 0.1N Sodium Thiosulfate ($Na_2S_2O_3$)
The method is adequate and satisfies the requirements under Guideline 830.1800.

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Colorless to slightly yellow	49672603	Y
.6303 Physical State	Clear liquid	49672603	Y
.6304 Odor	Chlorine-like	49672603	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	This product will not come into contact with metal or metal ions.	49840201	N/A
.6314 Oxidation/Reduction Chemical Incompatibility	Agent / Compatibility: Water – compatible; 10% Monoammonium phosphate solution – compatible; Iron powder – compatible; 10% Potassium permanganate solution – compatible; Kerosene – compatible	49672603	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	49840201	N/A
.6316 Explodability	The product is not potentially explosive.	49840201	N/A
.6317 Storage Stability	Stable for 30 days at T=40°C	49672604	N (See Finding 8)
.6319 Miscibility	The product is not to be mixed with petroleum distillate.	49840201	N/A
.6320 Corrosion Characteristics	Not corrosive after 1 month of storage at T=40°C	49672604	N (See Finding 8)
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	49840201	N/A
.7000 pH	5.44	49672603	Y
	4.0 – 6.0	CSF	
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	1.0 Centistokes @20.0°C; 0.7 Centistokes @40.0°C	49672603	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.005 g/mL @ 20°C	49672603	Y
	1.01 – 1.07 g/mL	CSF	

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Confidential Appendix A

830.1550. Product Identity and Composition

EPA Reg. No. 91685-R is an end-use product, containing the active ingredients Hypochlorous Acid, CAS No. 7790-92-3 with a label claim nominal concentration of 0.45%, and other ingredients content of 99.55%. The product is intended to reduce bacterial pathogens on processed fruit and vegetable surfaces. The product is produced by an integrated system. The requirements of Guideline 830.1550 are satisfied.

830.1600. Description of Materials Used to Produce the Product

Description of Materials Used to Produce the Product provided in MRID 49672601 does not contain a solvent. The requirements of Guideline 830.1600 are not satisfied.

830.1620. Description of Production Process

As per MRID 49672601, the product is ready for sell and distribution after some time delay from the date of production and packaging. However, the time delay value is not provided. Additionally, the Description is not accompanied with chemical equations describing scientifically the production process with evaluation of by-products. The requirements of Guideline 830.1620 are not satisfied.

830.1670. Discussion of Formation of Impurities

Data provided in MRID 49672601 describe the formation of impurities during the production process not based on established chemical theory without providing chemical equations pertained to the current production process. The study only mentioned [redacted] in the product but no data about its amount (concentration) are provided. The requirements of Guideline 830.1670 are not satisfied.

830.1700. Preliminary Analysis

Preliminary Analysis data are provided in MRID 49672602 and are listed in the table below. The study is not acceptable because the analysis did not evaluate [redacted] mentioned in section Discussion of Formation of Impurities of MRID 49672601 as well as other possible by-products.

Manufacturing process information may be entitled to confidential treatment

Summary of Composition			
Test Substance ID	Batch No.	%Hypochlorous acid	% Free Available Chlorine (FAC)
ProduceFresh Produce Quality Treatment Solution	VP-1 032415	0.46	0.62
	VP-2 032415	0.50	0.68
	VP-3 032415	0.42	0.56
	VP-4 032415	0.42	0.57
	VP-5 032415	0.46	0.63

The requirements of Guideline 830.1700 are not satisfied.

830.1750. Certified Limits

As per MRID 49672601, the upper certified limit (0.5%) has been fitted equal to the production concentration and it is not based on the nominal concentration pertained to ready-to-use product and/or Preliminary Analysis data. The lower certified limit (0.3%) is based on the result of accelerated storage stability test that is not acceptable due to a temperature deviation from the standard requirements. Therefore, the requirements of Guideline 830.1750 are not acceptable.

Notes to PM:

1. The substance tested for group B data and described in MRID 49672603 has a higher level of the nominal concentration compared with the same on the CSF and the label (0.65% vs 0.45%). Additionally, the test substance contains an impurity [redacted] that is not shown in the formulation and has not been evaluated during the studies. Thus, the group B data are questionable.

2. As per the cover letter dated 08/27/2015, the chemical equation provided in section Chemistry evaluates by-product [redacted] that was not found under Preliminary Analysis and is not mentioned in Discussion of Formation of Impurities.

3. As per the current CSF, it looks like the product is created by [redacted] with the active ingredient that is not in compliance with Description of Production Process provided in MRID 49672601.

Decision #: 508635
DP #: (430257)
PRIA
Parent DP #:
Submission #: 973503
E-Sub #: 8299

DATA PACKAGE BEAN SHEET

Date: 20-Nov-2015

* * * Registration Information * * *

Registration: 91685-R - ProduceFresh Produce Quality Treatment Solution

Company: 91685 - PURICORE INC
Risk Manager: RM 32 - Demson Fuller - (703) 308-8062 Room# PY1 S-8834
Risk Manager Reviewer: Srinivas Gowda SGOWDA
Sent Date: PRIA Due Date: 13-Feb-2017 Edited Due Date:
Type of Registration: Product Registration - Section 3
Action Desc: (A460) NEW USE,NEW FOOD USE,WITH TOLERANCE EXEMPTION
Ingredients: 129054, Hypochlorous Acid(.45%)

* * * Data Package Information * * *

Expedite: Yes ● No Date Sent: 20-Nov-2015 Due Back:
DP Ingredient: 129054, Hypochlorous Acid

DP Title: Product Chemistry
CSF Included: Yes ● No Label Included: Yes ● No Parent DP #:

Assigned To **Date In** **Date Out**

Organization: AD / PSB
Team Name: CTT
Reviewer Name:
Contractor Name:

Last Possible Science Due Date: 01-Oct-2016
Science Due Date:
Sub Data Package Due Date:

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

This is a PRIA action. The Technical Screen ends on 2/9/16.

Please review the Product Chemistry data in support of this application. Data and other information to support this application can be found on documentum.

If you have any questions, please touch base with Srini Gowda. Thanks.
Demson

PC

DP# (430257) • • • Studies Sent for Review • • • Decision#. (508635)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1550/Product Identity and composition	Pass (10-Sep-2015)
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1600/Description of materials used to produce the product	Pass (10-Sep-2015)
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1620/Description of production process	Pass (10-Sep-2015)
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1650/Description of formulation process	Pass (10-Sep-2015)
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1670/Discussion of formation of impurities	Pass (10-Sep-2015)
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1750/Certified limits	Pass (10-Sep-2015)
49672601		Solomon, E. (2015) Group A Product Chemistry For ProduceFresh(R) Produce Quality Treatment Solution. Project Number: PURICORE/072815A. Unpublished study prepared by Puricore Inc. 35p.	830.1800/Enforcement analytical method	Pass (10-Sep-2015)
49672602		Bellizio, J. (2015) ProduceFresh Produce Quality Treatment Solution: Preliminary Analysis, Active Ingredient Only. Project Number: 40710, P809/AI. Unpublished study prepared by Product Safety Laboratories. 30p.	830.1700/Preliminary analysis	Pass (10-Sep-2015)
49672603		Wo, C. (2015) PuriCore Produce Concentrate: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density. Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.6302/Color	Pass (10-Sep-2015)
49672603		Wo, C. (2015) PuriCore Produce Concentrate: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density. Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.6303/Physical state	Pass (10-Sep-2015)
49672603		Wo, C. (2015) PuriCore Produce Concentrate: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density. Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.6304/Odor	Pass (10-Sep-2015)
49672603		Wo, C. (2015) PuriCore Produce Concentrate: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density. Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.6314/Oxidizing or reducing action	Pass (10-Sep-2015)

DP# (430257) · · · Studies Sent for Review · · · Decision# (508635)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49672603		Wo, C (2015) PuriCore Produce Concentrate Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.7000/pH	Pass (10-Sep-2015)
49672603		Wo, C (2015) PuriCore Produce Concentrate Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.7100/Viscosity	Pass (10-Sep-2015)
49672603		Wo, C (2015) PuriCore Produce Concentrate Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscocity, and Density/Relative Density Project Number: 40012, P80. Unpublished study prepared by Product Safety Laboratories. 25p.	830.7300/Density/relative density	Pass (10-Sep-2015)
49672604		Bellizio, J. (2015) ProduceFresh Produce Quality Treatment Solution: Accelerate Storage Stability and Corrosion Characteristics. Project Number: 41166, P802. Unpublished study prepared by Product Safety Laboratories. 26p.	830.6317/Storage stability	Pass (10-Sep-2015)
49672604		Bellizio, J. (2015) ProduceFresh Produce Quality Treatment Solution: Accelerate Storage Stability and Corrosion Characteristics. Project Number: 41166, P802. Unpublisned study prepared by Product Safety Laboratories. 26p.	830.6320/Corrosion characteristics	Pass (10-Sep-2015)

Pages 90-95 Claimed confidential by submitter

Exponent

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

February 23, 2016

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: **Srinivas Gowda, Reviewer/Risk Manager**

Subject: **Response to Technical Screen 10-Day Deficiency Letter (Decision No. 508635)**
ProduceFresh® Produee Quality Treatment Solution
EPA File Symbol: 91685-R

Dear Mr. Fuller:

On behalf of our client, Puricore Inc. (508 Lapp Road, Malvern, PA 19355, EPA Company Number 91685), Exponent is responding to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

In response to the Agency's letter, Puricore Inc. is providing additional information for each deficiency identified in order to continue the review of this pending application. Responses to each of the efficacy, product chemistry, toxicology and dietary risk assessment technical screen deficiencies listed in the Agency's letter dated February 9, 2016, are enclosed.

Please note that the information in this letter is considered ***Confidential Business Information*** and must not be disclosed to any party outside of EPA. If you have any questions regarding this submission, please contact me at 202-772-4919 or ncowen@exponent.com.

Sincerely,

Nicola D. Cowen, M.Sc.
Authorized Representative of
Puricore Inc.

Enclosures

cc: Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
James B. Messina, Exponent

Claimed confidential by submitter

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ **Registration** ☐ **Amendment** ☒ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: **91685-R**
2. EPA Product Manager: **Demson Fuller**
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): **Puricore Inc. / ProduceFresh® Produce Quality Treatment Solution**
5. PM# **32**
5. Name and Address of Applicant *(Include ZIP Code)*: **Puricore Inc. 508 Lapp Road Malvern, PA 19355**
☐ *Check if this is a new address*
6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated XX-XX-XX
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: ☐ Yes* ☒ No
***Certification must be submitted**

Unit Packaging: ☐ Yes ☒ No
If "Yes" Unit Packaging wgt. **5 gallons** | No. per Container **2 (2.5 gallon containers)**

Water Soluble Packaging: ☐ Yes ☒ No
If "Yes" Package wgt. | No. per Container

2. Type of Container: ☐ Metal ☒ Plastic ☐ Glass ☐ Paper/cardboard ☐ Other (Specify) Plastic Bag

3. Location of Net Contents Information: ☒ Label ☐ Container

4. Size(s) Retail Container: **2.5 gallons**

5. Location of Label Directions: ☒ On Labeling ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Other _____ ☒ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ethan Solomon	**Associate Director, Research & Development**	**(484) 321-2724**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature: Ethan B. Solomon
3. Title: **Associate Director, Research & Development**
4. Typed Name: **Ethan Solomon**
5. Date: **February 23, 2016**

ProduceFresh® Produce Quality Treatment Solution

Antimicrobial Fruit and Vegetable Wash

For use in retail establishments and commercial or institutional settings, such as grocery stores, convenience stores, kitchens, and food service operations.

Water additive for pathogen reduction in fruit and vegetable wash or process waters

Controls bacterial pathogens (*Escherichia coli, Salmonella enterica,* and *Listeria monocytogenes*) in hydrating and crisping water for fruits and vegetables

Controls spoilage and decay-causing bacteria in fruit and vegetable wash or process waters

Controls spoilage and decay-causing non-public health microorganisms on processed fruit or vegetable surfaces and wash or process waters

Reduces bacterial pathogens on processed fruit and vegetable surfaces

Active Ingredient:	
Hypochlorous Acid*	0.45%
Inert Ingredients	99.55%
Total	100.00%

*Contains 6000 ppm (0.6%) Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center 1-800-222-1222.	

Manufactured by:
Puricore Inc.
508 Lapp Road
Malvern, PA 19355
Ph: +1.484.321.2700

EPA Reg. No.: 91685-R
EPA Est. No.: 91685-PA-001

Net Contents: _____ gal

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

When used as directed under EPA regulations, ProduceFresh® Produce Quality Treatment Solution will:

- [Reduce] [Kill] 99.999% of *Escherichia coli* O157:H7 (ATCC 43895, 35150, 43890), *Salmonella enterica* (ATCC 10721, 6962, 13311), and *Listeria monocytogenes* (ATCC 49594, 19114, 19116) in [hydrating and crisping water] [and] [wash or process water] for fruits and vegetables
- [Controls] [Kills] spoilage and decay causing non-public health microorganisms present in the wash or process water for fruit and vegetable raw agricultural commodities (RACs)
- Control spoilage and decay causing non-public health bacteria in fruit or vegetable wash or process waters
- Control the growth of spoilage and decay causing non-public health bacteria in wash or process water for fruits and vegetables
- Reduces cross contamination of fruits and vegetables from the wash or process water
- Protects against cross contamination in the produce wash water

To treat the surface of *processed* fruits and vegetables (FDA Regulations):

This product may be used in wash water to reduce the pathogens *Escherichia coli O157:H7* (ATCC 43895, 35150, 43890), *Listeria monocytogenes* (ATCC 49594, 19114, 19116), and *Salmonella enterica* (ATCC 10721, 6962, 13311) on the surface of processed fruits and vegetables introduced during handling or processing

- ProduceFresh® Produce Quality Treatment Solution will control the growth of spoilage and decay-causing non-public health microorganisms on processed fruits and vegetables
- Reduce the level of pathogens (*Eschericia coli O157:H7, Listeria monocytogenes, Salmonella enterica*) on the surfaces of processed fruits and vegetables
- Protects against cross contamination of pathogens and spoilage organisms
- Reduces surface residues of organic matter and bacteria

- Reduces the potential for cross contamination and increases the freshness of store-prepared [whole] [and] [cut] fruit and vegetable programs

This use must comply with all applicable FDA regulations, including, but not limited to 21 CFR 173.405, 21 CFR 184.1061, and 21 CFR 170.3.

Use Instructions:

1) Add ProduceFresh® Produce Quality Treatment Solution into processing sink using nozzle connected to the wall-mount dilution system. The wall-mounted diluter provides a solution of ProduceFresh® Produce Quality Treatment Solution containing approximately 30 - 60 parts per million (ppm) of free available chlorine (FAC).

2) Place desired fruits or vegetables (cut or whole) into sink containing ProduceFresh® Produce Quality Treatment Solution. Soak for a minimum of 90 seconds. Remove produce from the solution and set aside to drain.

3) Alternatively, ProduceFresh® Produce Quality Treatment Solution may be introduced onto fruits and vegetables (cut or whole) by rinsing or spraying the solution for a minimum of 90 seconds onto the produce using the supplied nozzle and allowing the solution to drain.

4) The ProduceFresh® Produce Quality Treatment Solution treatment process is continued until all produce requiring treatment (hydration or crisping) is complete.

5) Produce may be used for display or consumed after 10 minutes of draining. No rinse is required.

Use Controls:

- The concentration of free available chlorine (FAC) shall range from 30 - 60 ppm. If the concentration of the solution falls below 30 ppm, the sink is drained and re-filled with fresh ProduceFresh® Produce Quality Treatment Solution using the wall-mount dilution system.

- Test strips are supplied to insure that the FAC of the treatment solution is maintained above 30 ppm. Use a test strip to ensure the treatment solution is above 30 ppm prior to use.

[To Clean and Deodorize]

[Misting Lines:]
- [Can be used in misting lines to keep them clean and free of odor-causing bacteria]
- [Maintains the cleanliness and freshness of water used to mist fresh produce]
- [Maintains the cleanliness of lines used to mist fresh produce]
- [Cleans spray nozzles to improve coverage of produce displayed at retail]

Alternate Brand Name:
ProduceFresh® Antimicrobal Produce Wash

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal, or cleaning of equipment.

Pesticide Storage: Store the product upright and away from sunlight. Keep container tightly closed and store in a cool, well-ventilated area.

Pesticide Disposal: Wastes from this use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

Batch Code XXXXXXX

Exponent

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Puricore Inc.
508 Lapp Road
Malvern, PA 19355

CONTACT PERSON (Return to):

Nicola Cowen
Authorized Representative of
Puricore Inc.
Exponent
1150 Connecticut Ave, N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is prepared to support a new end-use product (PRIA A540) for:

ProduceFresh® Produce Quality Treatment Solution, EPA Reg. No. 91685-R

SUBMITTAL DATE:

August 26, 2015

Volume	Study Title	MRID No.
1	Administrative Materials	49672600
2	Group A Product Chemistry For ProduceFresh Produce Quality Treatment Solutions; Solomon E., (2015); Study No.: 072815A. EPA Guidelines OPPTS 830.1550; 830.1600; 830.1620; 830.1650; 830.1670; 830.1750; 830.1800.	49672601
3	ProduceFresh Produce Quality Treatment Solutions: Preliminary Analysis, Active Ingredient Only; Bellizio J., (2015); Study No.: 40710. EPA Guideline OPPTS 830.1700.	49672602
4	Puricore Produce Concentrate: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity and Relative Density; Woo C., (2015); Study No.: 40012. EPA Guideline OPPTS 830.6302; 830.6303; 830.6304; 830.6314; 830.7000; 830.7100; 830.7300.	49672603

Volume	Study Title	MRID No.
5	ProduceFresh Produce Quality Treatment Solution: Accelerated Storage Stability and Corrosion Characteristics; Bellizio J., (2015); Study No.: 41166. EPA Guidelines OPPTS 830.6317 and 830.6320.	49672604
6	Puricore Produce Concentrate: Acute Oral Toxicity - Up-And-Down Procedure in Rats; Lowe C., (2015); Study No.: 40013. EPA Guidelines OPPTS 870.1100.	49672605
7	Puricore Produce Concentrate: Acute Dermal Toxicity in Rats; Lowe C., (2015); Study No.: 40014. EPA Guidelines OPPTS 870.1200.	49672606
8	Acute Inhalation Toxicity Waiver Request for ProduceFresh™; Solomon E., (2015); Study No.: PURICORE 32014. EPA Guidelines OPPTS 870.1300.	49672607
9	Puricore Produce Concentrate: Primary Eye Irritation in Rabbits; Lowe C., (2015); Study No.: 40015. EPA Guidelines OPPTS 870.2400.	49672608
10	Puricore Produce Concentrate: Primary Skin Irritation in Rabbits; Lowe C., (2015); Study No.: 40016. EPA Guidelines OPPTS 870.2500.	49672609
11	Puricore Produce Concentrate: Dermal Sensitization Test in Guinea Pigs - Buehler Method; Lowe C., (2015); Study No.: 40017. EPA Guidelines OPPTS 870.2600.	49672610
12	Modified EPA Food Contact Sanitizer Test for Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of Disinfectants); Mastej J., (2015); Study No.: GR3250. EPA DIS/TSS-4.	49672611
13	ProduceFresh Produce Quality Treatment Solution: Enforcement Analytical Method for the Determination of Hypochlorous acid and Free Available Chlorine by Titration Bellizio J., (2015); Study No.: 41166 EAM. EPA Guideline OPPTS 830.1800.	49672612

Exponent

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Puricore Inc.
508 Lapp Road
Malvern, PA 19355

CONTACT PERSON (Return to):

Nicola Cowen
Authorized Representative of
Puricore Inc.
Exponent
1150 Connecticut Ave, N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016. Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

SUBMITTAL DATE:

February 23, 2016

Volume	Study Title	MRID No.
1	Administrative Materials	49840200
2	Group B Product Chemistry For Puricore Inc.'s ProduceFresh® Produce Quality Treatment Solution; Solomon E., (2016); Study No.: PURICORE022016. EPA Guidelines OCSPP 830.6313; 830.6315; 830.6316; 830.6319; 830.6321; and 830.7520.	49840201
3	ProduceFresh® Produce Quality Treatment Solution: Acute Inhalation Toxicity in Rats; Lowe C., (2016); Study No.: 42666. EPA Guidelines OCSPP 870.1300.	49840202

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: February 23, 2016 | **EPA Reg. No./File Symbol: 91685-R** |

Applicant's/Registrant's Name and Address: Puricore Inc.
508 Lapp Road
Malvern, PA 19355

Product Name: ProduceFresh® Produce Quality Treatment Solution Containing

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.7000	pH	49672603	Puricore Inc.	OWN	
830.7100	Viscosity	49672603	Puricore Inc.	OWN	
830.7300	Density/relative density/bulk density	49672603	Puricore Inc.	OWN	
830.7520	Particle size, fiber length, and diameter distribution	49840201	Puricore Inc.	OWN	
§ 158.2230: Toxicology Data Requirements					
870.1100	Acute oral toxicity	49672605	Puricore Inc.	OWN	
870.1200	Acute dermal toxicity	49672606	Puricore Inc.	OWN	
870.1300	Acute inhalation toxicity	49672607 49840202	Puricore Inc.	OWN	
870.2400	Primary eye irritation	49672608	Puricore Inc.	OWN	
870.2500	Primary dermal irritation	49672609	Puricore Inc.	OWN	
870.2600	Dermal sensitization	49672610	Puricore Inc.	OWN	
§ 158.2220: Product Performance Data Requirements					
810.2000	*Escherichia coli (ATCC 35150, 43890, and 43895)* *Salmonella Enterica* (ATCC 6962, 10721, and 13311) *Listeria monocytogenes* (ATCC 19114, 19116, and 49594)	49672611	Puricore Inc.	OWN	

[redacted]

Signature:	Name and Title: Ethan Solomon Associate Director, Research & Product Development	Date: Feb 23, 2016

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. ■ Agency Internal Use Copy ☐ Public File Copy

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: February 23, 2016	**EPA Reg. No./File Symbol: 91685-R**	**Page 1 of 2**
Applicant's/Registrant's Name and Address: **Puricore Inc.** **508 Lapp Road** **Malvern, PA 19355**	**Product Name:** **ProduceFresh® Produce Quality Treatment Solution Containing**	
Ingredients: Hypochlorous acid (CAS# 7790-92-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
§ 158.2210: Product Chemistry Data Requirements					
830.1550	Product identity and composition	49672601	Puricore Inc.	OWN	
830.1600	Description of materials used to produce the product	49672601	Puricore Inc.	OWN	
830.1620	Description of production process	49672601	Puricore Inc.	OWN	
830.1650	Description of formulation process	49672601	Puricore Inc.	OWN	
830.1670	Discussion of formation of impurities	49672601	Puricore Inc.	OWN	
830.1700	Preliminary analysis	49672602	Puricore Inc.	OWN	
830.1750	Certified limits	49672601	Puricore Inc.	OWN	
830.1800	Enforcement analytical method	49672601 49672612	Puricore Inc.	OWN	
830.1900	Submittal of samples		Submitted upon request		
Physical and Chemical Properties					
830.6302	Color	49672603	Puricore Inc.	OWN	
830.6303	Physical state	49672603	Puricore Inc.	OWN	
830.6304	Odor	49672603	Puricore Inc.	OWN	
830.6313	Stability (normal/elevated temperatures, metals and ions)	49840201	Puricore Inc.	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	49672603	Puricore Inc.	OWN	
830.6315	Flammability	49840201	Puricore Inc.	OWN	
830.6316	Explodability	49840201	Puricore Inc.	OWN	
830.6317	Storage stability	49672604	Puricore Inc.	OWN	
830.6319	Miscibility	49840201	Puricore Inc.	OWN	
830.6320	Corrosion characteristics	49672604	Puricore Inc.	OWN	
830.6321	Dielectric breakdown voltage	49840201	Puricore Inc.	OWN	

Signature: Ethan B. Solomon	**Name and Title:** **Ethan Solomon** **Associate Director,** **Research & Product Development**	**Date:** **Feb 23, 2016**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. ■ Agency Internal Use Copy ❒ Public File Copy

71685 - R

Memorandum

Date: 5/5/16

To: PM 32, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 03, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

EXPONENT, INC.
PURICORE INC.
1150 CONN. AVE., NW, SUITE 1100
WASHINGTON, DC 20036

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 29-APR-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 985514 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 91685 PURICORE INC.

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 32

Product #: 91685-R Product Name: ProduceFresh Produce Quality Treatment Sol

Override#

Me Too Section3:

Me Too Product Name:

Application Date: 29-Apr-2016

Front End Date: 02-May-2016

FFS Due Date:

OPP Target Date:

OPP Rec'vd Date: 29-Apr-2016

Risk Manager Send Date: 02-May-2016

Negotiated Due Date:

Receipt Content	Des
Study	

Fast Track:

New Ingredient:

View/Edit

Receipt Description:

new efficacy data in response to technical screen deficiency

New Ingredient Request Date

New Ingredient Received Date

Form A Signature Date

Form B Signature Date

Exponent®

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

April 29, 2016

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: **Srinivas Gowda, Reviewer/Risk Manager**

Subject: **New Efficacy Data Submission in Response to Technical Screen Deficiency (Decision No. 508635)**
ProduceFresh® Produce Quality Treatment Solution
EPA File Symbol: 91685-R

Dear Mr. Fuller:

On behalf of our client, Puricore Inc. (508 Lapp Road, Malvern, PA 19355, EPA Company Number 91685), Exponent is submitting a new efficacy study in response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application for ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R). The new efficacy study provided with this submission confirms the previous results (same 5 log reduction) from the submitted efficacy study with MRID 49672611.

The Agency determined the following issue with the previously submitted efficacy study (MRID 49672611):

> "The vegetable soil load was made with vegetables cut into small pieces, however the appropriate vegetable soil load to support this claim consists of vegetables (tomato, carrot, and iceberg lettuce) blended in a blender."

After several communications with the Agency, EPA agreed to allow Puricore to submit confirmatory test data, blending the vegetable soil load, to address the concerns from the 90 Day Technical Screen. Since the PRIA due date is not until February 2017, submission of this new confirmatory efficacy data will not delay the schedule. A copy of the email from EPA is enclosed.

Please find enclosed the following documentation in support of this response:

- Application for Pesticide Registration (EPA Form 8570-1);
- Transmittal Document;
- Data Citation (EPA Form 8570-34);
- Data Matrix (EPA Form 8570-35, EPA and Public Versions); and
- Efficacy Study.

If you have any questions regarding this submission, please contact me at 202-772-4919 or ncowen@exponent.com.

Sincerely,

Nicola D. Cowen, M.Sc.
Authorized Representative of
Puricore Inc.

Enclosures

cc: Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
James Messina, Exponent

From: Fuller, Demson
To: Nicola Cowen
Cc: Gowda, Srinivas; Clune, Alison; Wormell, Lance; Perry, Mark
Subject: Conference Call This Morning/Follow-Up
Date: Thursday, March 31, 2016 12:36:09 PM

Hi Niki,

It was a pleasure speaking with you this morning to address the efficacy concerns with File Symbol 91685-R (Produce Fresh) . To follow up, you proposed that your client, Puricore, would like to submit confirmatory test data to address the concerns from the 90 Day Technical Screen. Since the PRIA due date is not until February 2017, you believe that you can provide this information to us quickly without delaying the schedule. You are committed to providing this data to us by 5/1/16. You will concurrently provide a courtesy copy in advance (electronically) and submit the data through front end processing so it can get an MRID number. If the data are submitted on time, we can move forward with conducting the review.

You also stated that if the data are deemed unacceptable, Puricore will remove the public health claims from the labeling and reflect only public health claims.

Let us know if you have any questions.
Demson

Demson Fuller

Product Manager, Team 32
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
(703)-308-8062

Exponent®

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Puricore Inc.
508 Lapp Road
Malvern, PA 19355

CONTACT PERSON (Return to):

Nicola Cowen
Authorized Representative of
Puricore Inc.
Exponent
1150 Connecticut Ave, N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Submission of New Efficacy Data in Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

SUBMITTAL DATE:

April 29, 2016

Volume	Study Title	MRID No.
1	Administrative Materials	
2	Modified EPA Food Contact Sanitizer Test for Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of Disinfectants); Mastej, J., (2016); Study No.: GR3321. EPA Guideline OCSPP 810.2000.	**49909701**

Exponent®

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

April 29, 2016

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: **Srinivas Gowda, Reviewer/Risk Manager**

Subject: **New Efficacy Data Submission in Response to Technical Screen Deficiency (Decision No. 508635)**
ProduceFresh® Produce Quality Treatment Solution
EPA File Symbol: 91685-R

Dear Mr. Fuller:

On behalf of our client, Puricore Inc. (508 Lapp Road, Malvern, PA 19355, EPA Company Number 91685), Exponent is submitting a new efficacy study in response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application for ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R). The new efficacy study provided with this submission confirms the previous results (same 5 log reduction) from the submitted efficacy study with MRID 49672611.

The Agency determined the following issue with the previously submitted efficacy study (MRID 49672611):

> "The vegetable soil load was made with vegetables cut into small pieces, however the appropriate vegetable soil load to support this claim consists of vegetables (tomato, carrot, and iceberg lettuce) blended in a blender."

After several communications with the Agency, EPA agreed to allow Puricore to submit confirmatory test data, blending the vegetable soil load, to address the concerns from the 90 Day Technical Screen. Since the PRIA due date is not until February 2017, submission of this new confirmatory efficacy data will not delay the schedule. A copy of the email from EPA is enclosed.

Please find enclosed the following documentation in support of this response:

- Application for Pesticide Registration (EPA Form 8570-1);
- Transmittal Document;
- Data Citation (EPA Form 8570-34);
- Data Matrix (EPA Form 8570-35, EPA and Public Versions); and
- Efficacy Study.

If you have any questions regarding this submission, please contact me at 202-772-4919 or ncowen@exponent.com.

Sincerely,

Nicola D. Cowen

Nicola D. Cowen, M.Sc.
Authorized Representative of
Puricore Inc.

Enclosures

cc: Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
James Messina, Exponent

From: Fuller, Demson
To: Nicola Cowen
Cc: Gowda, Srinivas; Clune, Alison; Wormell, Lance; Perry, Mark
Subject: Conference Call This Morning/Follow-Up
Date: Thursday, March 31, 2016 12:36:09 PM

Hi Niki,

It was a pleasure speaking with you this morning to address the efficacy concerns with File Symbol 91685-R (Produce Fresh) . To follow up, you proposed that your client, Puricore, would like to submit confirmatory test data to address the concerns from the 90 Day Technical Screen. Since the PRIA due date is not until February 2017, you believe that you can provide this information to us quickly without delaying the schedule. You are committed to providing this data to us by 5/1/16. You will concurrently provide a courtesy copy in advance (electronically) and submit the data through front end processing so it can get an MRID number. If the data are submitted on time, we can move forward with conducting the review.

You also stated that if the data are deemed unacceptable, Puricore will remove the public health claims from the labeling and reflect only public health claims.

Let us know if you have any questions.
Demson

Demson Fuller

Product Manager, Team 32
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
(703)-308-8062

Exponent®

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Puricore Inc.
508 Lapp Road
Malvern, PA 19355

CONTACT PERSON (Return to):

Nicola Cowen
Authorized Representative of
Puricore Inc.
Exponent
1150 Connecticut Ave, N.W.
Suite 1100
Washington, DC 20036

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Submission of New Efficacy Data in Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

SUBMITTAL DATE:

April 29, 2016

Volume	Study Title	MRID No.
1	Administrative Materials	
2	Modified EPA Food Contact Sanitizer Test for Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of Disinfectants); Mastej, J., (2016); Study No.: GR3321. EPA Guideline OCSPP 810.2000.	**49909701**

Administrative Materials

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: **91685-R**

2. EPA Product Manager: **Demson Fuller**

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): **Puricore Inc. / ProduceFresh® Produce Quality Treatment Solution**

5.PM# **32**

5. Name and Address of Applicant *(Include ZIP Code)*
Puricore Inc.
508 Lapp Road
Malvern, PA 19355

☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated XX-XX-XX

☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated XX-XX-XX

☐ "Me Too" Application

☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of New Efficacy Data in Response to the Agency's Technical Screen 10-Day Deficiency Letter dated February 9, 2016, Decision No. 508635 for the pending application ProduceFresh® Produce Quality Treatment Solution (EPA File Symbol: 91685-R).

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No		☐ Yes ☒ No		☐ Metal ☒ Plastic ☐ Glass ☐ Paper/cardboard ☐ Other (Specify) Plastic Bag
**Certification must be submitted*	If "Yes" Unit Packaging wgt. **5 gallons**	No. per Container **2 (2.5 gallon containers)**	If "Yes" Package wgt.	No. per Container	

3. Location of Net Contents Information: ☒ Label ☐ Container

4. Size(s) Retail Container: **2.5 gallons**

5. Location of Label Directions: ☒ On Labeling ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Other _____ ☒ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ethan Solomon	Associate Director, Research & Development	(484) 321-2724

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature: Ethan B. Solomon

3. Title: **Associate Director, Research & Development**

4. Typed Name: **Ethan Solomon**

5. Date: **April 29, 2016**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Puricore Inc. **508 Lapp Road** **Malvern, PA 19355**	**91685-R**
Active Ingredient(s) and/or representative test compound(s) **Hypochlorous Acid**	Date **April 29, 2016**
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) **Fruit and Vegetable Wash for Commercial Use**	Product Name **ProduceFresh® Produce Quality Treatment Solution**

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature	Date	Typed or Printed Name and Title
Ethan B. Solomon	**April 29, 2016**	**Ethan Solomon** **Associate Director, Research & Development**

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: April 29, 2016

EPA Reg. No./File Symbol: 91685-R

Applicant's/Registrant's Name and Address: Puricore Inc.
508 Lapp Road
Malvern, PA 19355

Product Name: ProduceFresh® Produce Quality Treatment Solution Containing

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
§ 158.2210: Product Chemistry Data Requirements					
830.1550	Product identity and composition	49672601	Puricore Inc.	OWN	
830.1600	Description of materials used to produce the product	49672601	Puricore Inc.	OWN	
830.1620	Description of production process	49672601	Puricore Inc.	OWN	
830.1650	Description of formulation process	49672601	Puricore Inc.	OWN	
830.1670	Discussion of formation of impurities	49672601	Puricore Inc.	OWN	
830.1700	Preliminary analysis	49672602	Puricore Inc.	OWN	
830.1750	Certified limits	49672601	Puricore Inc.	OWN	
830.1800	Enforcement analytical method	49672601 49672612	Puricore Inc.	OWN	
830.1900	Submittal of samples		Submitted upon request		
Physical and Chemical Properties					
830.6302	Color	49672603	Puricore Inc.	OWN	
830.6303	Physical state	49672603	Puricore Inc.	OWN	
830.6304	Odor	49672603	Puricore Inc.	OWN	
830.6313	Stability (normal/elevated temperatures, metals and ions)	49840201	Puricore Inc.	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	49672603	Puricore Inc.	OWN	
830.6315	Flammability	49840201	Puricore Inc.	OWN	
830.6316	Explodability	49840201	Puricore Inc.	OWN	
830.6317	Storage stability	49672604	Puricore Inc.	OWN	
830.6319	Miscibility	49840201	Puricore Inc.	OWN	
830.6320	Corrosion characteristics	49672604	Puricore Inc.	OWN	
830.6321	Dielectric breakdown voltage	49840201	Puricore Inc.	OWN	

Signature: Ethan B. Solomon

Name and Title: Ethan Solomon
Associate Director,
Research & Product Development

Date: April 29, 2016

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: April 29, 2016	EPA Reg. No./File Symbol: 91685-R	Page 2 of 2
Applicant's/Registrant's Name and Address: Puricore Inc. 508 Lapp Road Malvern, PA 19355	Product Name: ProduceFresh® Produce Quality Treatment Solution Containing	

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.7000	pH	49672603	Puricore Inc.	OWN	
830.7100	Viscosity	49672603	Puricore Inc.	OWN	
830.7300	Density/relative density/bulk density	49672603	Puricore Inc.	OWN	
830.7520	Particle size, fiber length, and diameter distribution	49840201	Puricore Inc.	OWN	
§ 158.2230: Toxicology Data Requirements					
870.1100	Acute oral toxicity	49672605	Puricore Inc.	OWN	
870.1200	Acute dermal toxicity	49672606	Puricore Inc.	OWN	
870.1300	Acute inhalation toxicity	49672607 49840202	Puricore Inc.	OWN	
870.2400	Primary eye irritation	49672608	Puricore Inc.	OWN	
870.2500	Primary dermal irritation	49672609	Puricore Inc.	OWN	
870.2600	Dermal sensitization	49672610	Puricore Inc.	OWN	
§ 158.2220: Product Performance Data Requirements					
810.2000	*Escherichia coli (ATCC 35150, 43890, and 43895)* *Salmonella Enterica* (ATCC 6962, 10721, and 13311) *Listeria monocytogenes* (ATCC 19114, 19116, and 49594)	49672611	Puricore Inc.	OWN	
810.2000	*Escherichia coli (ATCC 35150, 43890, and 43895)* *Salmonella Enterica* (ATCC 6962, 10721, and 13311) *Listeria monocytogenes* (ATCC 19114, 19116, and 49594)	Pending	Puricore Inc.	OWN	

Signature:	Name and Title: Ethan Solomon Associate Director, Research & Product Development	Date: April 29, 2016

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: April 29, 2016	EPA Reg. No./File Symbol: 91685-R	Page 1 of 2
Applicant's/Registrant's Name and Address: Puricore Inc. 508 Lapp Road Malvern, PA 19355	Product Name: ProduceFresh® Produce Quality Treatment Solution Containing	
Ingredients: Hypochlorous acid (CAS# 7790-92-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
[redacted]					
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Submitted upon request		
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	

Signature:	Name and Title: Ethan Solomon Associate Director, Research & Product Development	Date: April 29, 2016
Ethan B. Solomon		

EPA Form 8570-35 (6-97) Electronic and Paper versions available. Submit only Paper version.

■ Agency Internal Use Copy ❒ Public File Copy

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: April 29, 2016

EPA Reg. No./File Symbol: 91685-R

Applicant's/Registrant's Name and Address: Puricore Inc.
508 Lapp Road
Malvern, PA 19355

Product Name: ProduceFresh® Produce Quality Treatment Solution Containing

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
[redacted]	[redacted]	[redacted]	Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	

Signature:	Name and Title:	Date:
Ethan B. Solomon	Ethan Solomon Associate Director, Research & Product Development	April 29, 2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 03, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. JAMES WILLIAMS
CHEMSTAR CORP
120 INTERSTATE WEST PARKWAY, SUITE 100
LITHIA SPRINGS, GA 30122

Dear Mr. Williams:

Subject: Transfer of Pesticide Registrations From Company Number **91685** to Company Number **46597**

Pursuant to your request in your letter and transfer agreement of October 07, 2016, we have approved the transfer of the following registrations from **PURICORE INC.**, company number **91685** to **CHEMSTAR CORP**, company number **46597**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
FloraFresh Floral Quality Care Solution	**91685-2**	**46597-3**

Pending Registered Products	Old EPA File Symbol	New EPA File Symbol
ProduceFresh Produce Quality Treatment Solution	**91685-R**	**46597-U**

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

By copy of this letter we are informing the transeror of these changes. If you have any questions, please contact Louis Vaughn at (703) 308-8114.

Sincerely,

Steve Robbins, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MR. NICOLA COWEN
EXPONENT, INC., AGENT FOR
PURICORE INC.
1150 CONN. AVE., NW, SUITE 1100
WASHINGTON, DC 20036

RE: L_91685_REG_46597_11_03_2016

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 8-27-15

Experts In-Processing Signature: B.B. Date 9-2-15 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 91685-R	EPA Receipt Date: 8-27-15

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Inerta approved for food use under 40 CFR 180.940, for use in antimicrobial formulations.

All forms are present.

PRN 11-03 review - Passed

Jacket - Passed

MRID - 496726

S-S/9-11-2015

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 1, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-508635
EPA File Symbol or Registration Number: 91685-R
Product Name: ProduceFresh Produce Quality Treatment Solution
EPA Receipt Date: 27-Aug-2015
EPA Company Number: 91685
Company Name: PURICORE INC.

MR. NICOLA COWEN
EXPONENT, INC.
PURICORE INC.
1150 CONN. AVE., NW, SUITE 1100
WASHINGTON, DC 20036-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6249.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service {973503È~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 32

Receipt No. S- 973503

EPA File Symbol/Reg. No. 91685-R

Pin-Punch Date: 8/27/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A540

Granted: A540

Amount Due: $ 4863

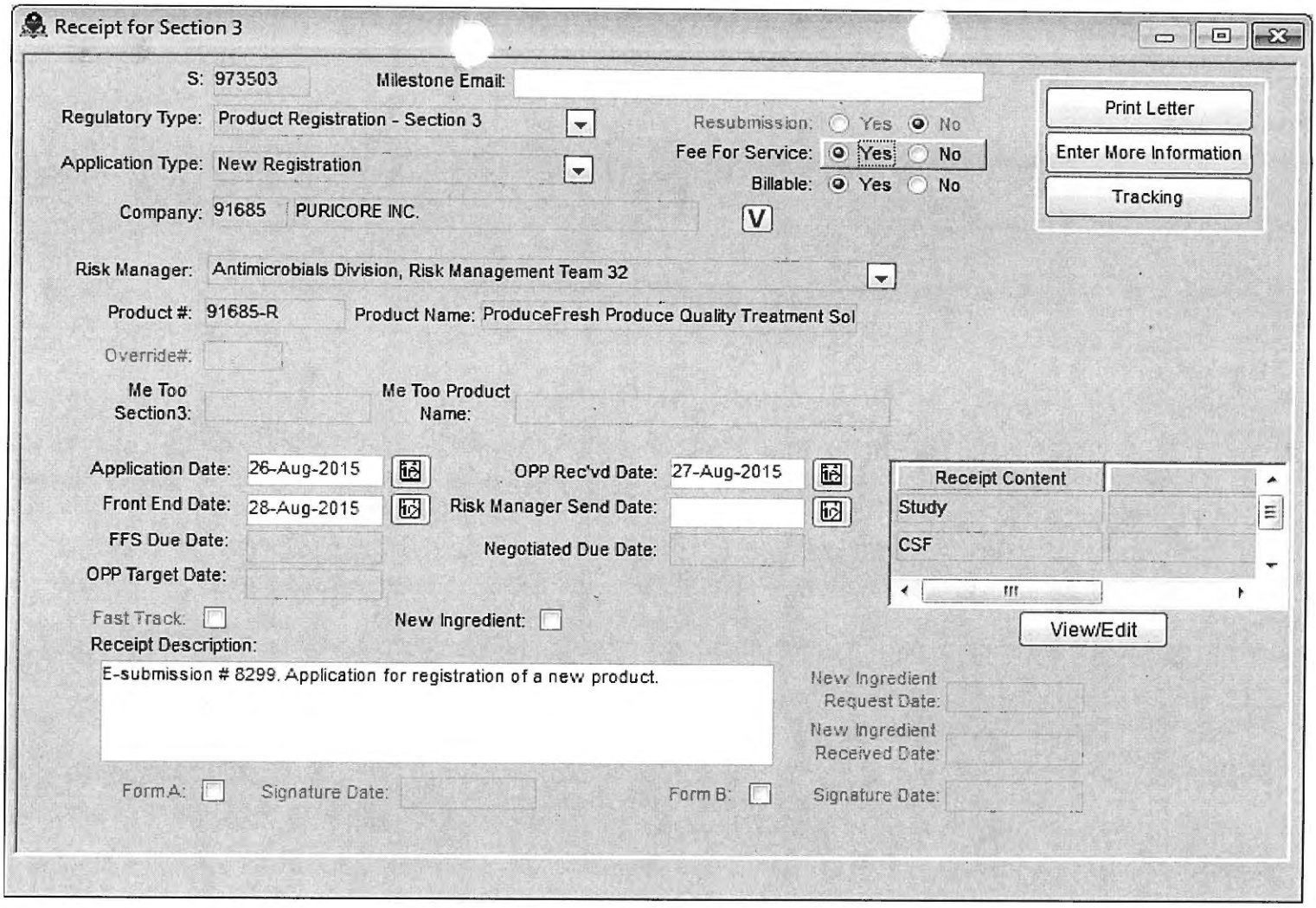
Inerts approved. SS/ 9-11

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Team 3 Date: 9/1/15

Remarks:


Receipt for Section 3
S: 973503
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 91685 PURICORE INC.
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 91685-R
Product Name: ProduceFresh Produce Quality Treatment Sol
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 26-Aug-2015
Front End Date: 28-Aug-2015
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 27-Aug-2015
Risk Manager Send Date:
Negotiated Due Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
E-submission # 8299. Application for registration of a new product.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

From: Ethan Solomon
To: Nicola Cowen
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Thursday, August 20, 2015 11:41:12 AM

-----Original Message-----
From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Thursday, August 20, 2015 11:38 AM
To: Ethan Solomon
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25MV2T46
Agency Tracking ID: 74859004006
Transaction Type: Sale
Transaction Date: 08/20/2015 11:38:00 AM EDT

Account Holder Name: Puricore Inc

Transaction Amount: $4,863.00
Billing Address: 508 Lapp Road
Billing Address 2:
City: Malvern
State/Province: PA
Zip/Postal Code: 19355
Country: USA
Card Type: AmericanExpress
Card Number: **********2004

Registration Number:
Company Name: Puricore Inc
Company Number: 91685
Action Code: A540

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

☒ Registration ☐ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: **91685-R**
2. EPA Product Manager: **Demson Fuller**
3. Proposed Classification: ☒ None ☐ Restricted
4. Company/Product (Name): **Puricore Inc. / ProduceFresh® Produce Quality Treatment Solution**
5. PM# **32**
5. Name and Address of Applicant *(Include ZIP Code)*: **Puricore Inc. 508 Lapp Road Malvern, PA 19355**
☐ *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated XX-XX-XX
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated XX-XX-XX
☐ "Me Too" Application
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
PRIA3 Code A540
Submission of a registration application for the New End-Use product registration ProduceFresh® Produce Quality Treatment Solution (EPA Reg. No. 91685-R).

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: ☐ Yes* ☒ No
Certification must be submitted

Unit Packaging: ☐ Yes ☒ No
If "Yes" Unit Packaging wgt.: **5 gallons** No. per Container: **2 (2.5 gallon containers)**

Water Soluble Packaging: ☐ Yes ☒ No
If "Yes" Package wgt. / No. per Container

2. Type of Container: ☐ Metal ☒ Plastic ☐ Glass ☐ Paper/cardboard ☐ Other (Specify) Plastic Bag

3. Location of Net Contents Information: ☒ Label ☐ Container
4. Size(s) Retail Container: **2.5 gallons**
5. Location of Label Directions: ☒ On Labeling ☐ On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Other _____ ☒ Paper glued ☐ Stenciled

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Ethan Solomon	Associate Director, Research & Development	(484) 321-2724

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature: Ethan B. Solomon
3. Title: **Associate Director, Research & Development**
4. Typed Name: **Ethan Solomon**
5. Date: **August 26, 2015**

Exponent®

1150 Connecticut Ave, NW
Suite 1100
Washington DC, 20036
Telephone: 202-772-4900
Facsimile: 202-772-4979
www.exponent.com

August 27, 2015

Demson Fuller, PM 32
Office of Pesticide Programs (7054P)
Document Processing Desk (REGFEE)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: **Submission of a Registration Application for the New End-Use Product ProduceFresh® Produce Quality Treatment Solution**
EPA File Symbol: 91685-R

Dear Mr. Fuller:

On behalf of our client, Puricore Inc. (508 Lapp Road, Malvern, PA 19355, EPA Company Number 91685), Exponent is submitting a new end-use registration application for the product ProduceFresh® Produce Quality Treatment Solution, containing the active ingredient hypochlorous acid at 0.45% (0.6% Free Available Chlorine).

Please find enclosed a CD the following documentation in support of this application:

- Application for Registration (EPA Form 8570-1);
- Transmittal Document;
- Confidential Statement of Formula (EPA Form 8570-4);
- Certification with Respect to Citation of Data (EPA Form 8570-34);
- Data Matrix (EPA Form 8570-35, EPA and Public Versions);
- Product Label ProduceFresh® Produce Quality Treatment Solution;
- Supporting Studies; and
- PRIA Category A540, Payment Confirmation Receipt, Pay.gov (Agency Tracking ID 74859004006; Pay.gov Tracking ID 25MV2T46).

If you have any questions regarding this submission, please contact me via telephone at 202-772-4919 or via email at ncowen@exponent.com.

Sincerely,

Nicola D. Cowen, M.Sc.
Authorized Representative of
Puricore Inc.

Enclosures

cc: Ethan Solomon, Puricore Inc.
Mark Sampson, Puricore Inc.
James B. Messina, Exponent

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Puricore Inc. **508 Lapp Road** **Malvern, PA 19355**	**91685-R**
Active Ingredient(s) and/or representative test compound(s) **Hypochlorous Acid**	Date **August 26, 2015**
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) **Fruit and Vegetable Wash for Commercial Use**	Product Name **ProduceFresh® Produce Quality Treatment Solution**

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose)	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitted to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.

Signature	Date	Typed or Printed Name and Title
Ethan B. Solomon	**August 26, 2015**	**Ethan Solomon** **Associate Director, Research & Development**

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: August 26, 2015	**EPA Reg. No./File Symbol: 91685-R**	**Page 1 of 2**
Applicant's/Registrant's Name and Address: Puricore Inc. 508 Lapp Road Malvern, PA 19355	**Product Name:** ProduceFresh® Produce Quality Treatment Solution Containing	

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
§ 158.2210: Product Chemistry Data Requirements					
830.1550	Product identity and composition	49672601	Puricore Inc.	OWN	
830.1600	Description of materials used to produce the product	49672601	Puricore Inc.	OWN	
830.1620	Description of production process	49672601	Puricore Inc.	OWN	
830.1650	Description of formulation process	49672601	Puricore Inc.	OWN	
830.1670	Discussion of formation of impurities	49672601	Puricore Inc.	OWN	
830.1700	Preliminary analysis	49672602	Puricore Inc.	OWN	
830.1750	Certified limits	49672601	Puricore Inc.	OWN	
830.1800	Enforcement analytical method	49672601 49672612	Puricore Inc.	OWN	
830.1900	Submittal of samples		Submitted upon request		
Physical and Chemical Properties					
830.6302	Color	49672603	Puricore Inc.	OWN	
830.6303	Physical state	49672603	Puricore Inc.	OWN	
830.6304	Odor	49672603	Puricore Inc.	OWN	
830.6313	Stability (normal/elevated temperatures, metals and ions)		Not expected to come into contact with metals and metal ions	N/A	
830.6314	Oxidation/reduction: chemical incompatibility	49672603	Puricore Inc.	OWN	
830.6315	Flammability		Does not contain combustible liquids	N/A	
830.6316	Explodability		Product is not potentially explosive	N/A	
830.6317	Storage stability	49672604	Puricore Inc.	OWN	

Signature: Ethan B. Solomon	**Name and Title:** Ethan Solomon Associate Director, Research & Product Development	**Date:** Aug 26, 2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. ■ Agency Internal Use Copy ❒ Public File Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: August 26, 2015	**EPA Reg. No./File Symbol: 91685-R**	**Page 2 of 2**
Applicant's/Registrant's Name and Address: Puricore Inc. 508 Lapp Road Malvern, PA 19355	**Product Name:** ProduceFresh® Produce Quality Treatment Solution Containing	
Ingredients: Hypochlorous acid (CAS# 7790-92-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.6319	Miscibility		Product is not an emulsifiable liquid and is not to be diluted with petroleum solvent	N/A	
830.6320	Corrosion characteristics	49672604	Puricore Inc.	OWN	
830.6321	Dielectric breakdown voltage		Product is not to be used around electrical equipment	N/A	
830.7000	pH	49672603	Puricore Inc.	OWN	
830.7100	Viscosity	49672603	Puricore Inc.	OWN	
830.7300	Density/relative density/bulk density	49672603	Puricore Inc.	OWN	
830.7520	Particle size, fiber length, and diameter distribution		Product is not a fibrous test substance	N/A	
§ 158.2230: Toxicology Data Requirements					
870.1100	Acute oral toxicity	49672605	Puricore Inc.	OWN	
870.1200	Acute dermal toxicity	49672606	Puricore Inc.	OWN	
870.1300	Acute inhalation toxicity	49672607	Puricore Inc.	OWN	
870.2400	Primary eye irritation	49672608	Puricore Inc.	OWN	
870.2500	Primary dermal irritation	49672609	Puricore Inc.	OWN	
870.2600	Dermal sensitization	49672610	Puricore Inc.	OWN	
§ 158.2220: Product Performance Data Requirements					
810.2000	*Escherichia coli (ATCC 35150, 43890, and 43895)* *Salmonella Enterica* (ATCC 6962, 10721, and 13311) *Listeria monocytogenes* (ATCC 19114, 19116, and 49594)	49672611	Puricore Inc.	OWN	

Signature: Ethan B. Solomon	**Name and Title:** Ethan Solomon Associate Director, Research & Product Development	**Date:** Aug 26, 2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

■ Agency Internal Use Copy ☐ Public File Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

EPA

Data Matrix

Date: August 26, 2015	EPA Reg. No./File Symbol: 91685-R	Page 1 of 2
Applicant's/Registrant's Name and Address: Puricore Inc. 508 Lapp Road Malvern, PA 19355	Product Name: ProduceFresh® Produce Quality Treatment Solution Containing	
Ingredients: Hypochlorous acid (CAS# 7790-92-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Submitted upon request		
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Not expected to come into contact with metals and metal ions	N/A	
			Puricore Inc.	OWN	
			Does not contain combustible liquids	N/A	
			Product is not potentially explosive	N/A	
			Puricore Inc.	OWN	

Signature:	Name and Title:	Date:
Ethan B. Solomon	Ethan Solomon Associate Director, Research & Product Development	Aug 26, 2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

☐ Agency Internal Use Copy ■ Public File Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Data Matrix

Date: August 26, 2015	EPA Reg. No./File Symbol: 91685-R	Page 2 of 2
Applicant's/Registrant's Name and Address: Puricore Inc. 508 Lapp Road Malvern, PA 19355	Product Name: ProduceFresh® Produce Quality Treatment Solution Containing	

Ingredients: Hypochlorous acid (CAS# 7790-92-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
[redacted]			Product is not an emulsifiable liquid and is not to be diluted with petroleum solvent	N/A	
			Puricore Inc.	OWN	
			Product is not to be used around electrical equipment	N/A	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Product is not a fibrous test substance	N/A	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	
			Puricore Inc.	OWN	

Signature: Ethan B. Solomon	Name and Title: Ethan Solomon Associate Director, Research & Product Development	Date: Aug 26, 2015

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. ☐ Agency Internal Use Copy ■ Public File Copy

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explodability	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		

Pages 147-148 Confidential Statement of Formula may be entitled to confidential treatment